



**Actemra<sup>®</sup> (tocilizumab)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Actemra<sup>®</sup> (tocilizumab) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Actemra<sup>®</sup> •**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

Intravenous (IV) formulation:

- Moderately to severely active rheumatoid arthritis (RA)
- Systemic juvenile idiopathic arthritis
- Polyarticular juvenile idiopathic arthritis (PJIA)

Subcutaneous (SQ) formulation:

- Moderately to severely active rheumatoid arthritis (RA)

**Approval Criteria**

Intravenous (IV) Formulation

- Patient is new to NHP and has been stabilized on IV Actemra<sup>®</sup> for an approvable indication

**OR**

- Patient is  $\geq 18$  years of age **AND**
- Patient has a diagnosis of moderately to severely active rheumatoid arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD\*, if methotrexate is contraindicated)

**OR**

- Patient is  $\geq 2$  years of age with a diagnosis of polyarticular juvenile idiopathic arthritis or active systemic juvenile idiopathic arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with the recommended initial and continued therapies (please refer to Appendices 1 & 2 below)

Subcutaneous (SQ) Formulation

- Patient is new to NHP and has been stabilized on SQ Actemra<sup>®</sup> for the approvable indication

**OR**

- Patient is  $\geq 18$  years if age **AND**
- Patient has a diagnosis of moderately to severely active rheumatoid arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with methotrexate. (or another DMARD\*, if methotrexate is contraindicated)

\* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

Initial approvals for both IV and SQ Actemra may be issued for up to 6 months with quantity limits appropriate for the patient consistent with weight-based dosing.

## Reauthorization Criteria

- Improvement per physician assessment of overall disease activity

Reauthorizations may be granted for up to 12 months.

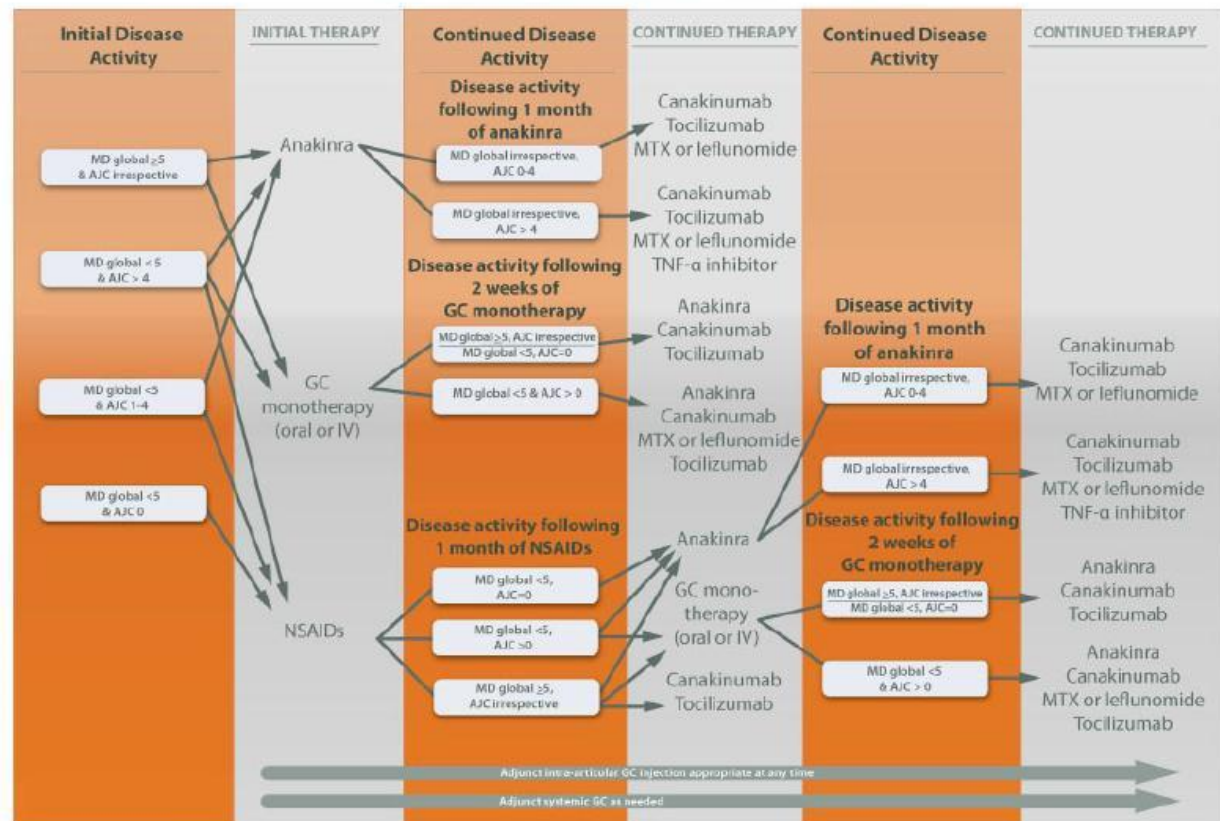
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- Genentech gains FDA approval for new subcutaneous formulation of Actemra® for use in adult patients living with moderately to severely active rheumatoid arthritis [press release on the internet]. Genentech. 2013 October 21. Available at: <http://www.gene.com/media/press-releases/14557/2013-10-21/genentech-gains-fda-approval-for-new-sub>
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Last reviewed/updated: 4/6/2015

## Appendix 1

### PATIENT WITH ACTIVE SYSTEMIC FEATURES & VARYING DEGREES OF SYNOVITIS



**Figure 1.** Treatment pathways for patients with active systemic features and varying degrees of synovitis. The Task Force Panel was asked to consider the treatments among patients with active systemic features and a physician global assessment (MD global) of  $< 5$  or  $\geq 5$  on a 10-point numerical rating scale (0–10 visual analog scale, where 0 = no disease activity and 10 = the most severe) and by active joint count (AJC; 0 joints, 1–4 joints, or  $> 4$  joints). If a recommendation is noted to be irrespective of the AJC or MD global, the recommendation was for children with an AJC  $\geq 0$  or an MD global  $> 0$ , respectively. Adjunct systemic glucocorticoids (GCs) and/or intraarticular GCs may be added at any point. Children may qualify for  $> 1$  pathway, in which case it is left to the provider's discretion to choose the path they feel is most appropriate based upon specific patient characteristics and/or patient and family preferences. Steps in the progression of therapy can be additive or sequential, except that therapies with a biologic agent are sequential (combination therapy with a biologic agent is not endorsed). The recommendations in this figure are for patients with active systemic features. If the systemic features (but not the arthritis) respond to therapy, then subsequent treatment decisions should be based upon the recommendations in Figure 2. NSAIDs = nonsteroidal antiinflammatory drugs; IV = intravenous; MTX = methotrexate; TNF $\alpha$  = tumor necrosis factor  $\alpha$ .

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512

## Appendix 2

### PATIENT WITHOUT ACTIVE SYSTEMIC FEATURES & VARYING DEGREES OF SYNOVITIS

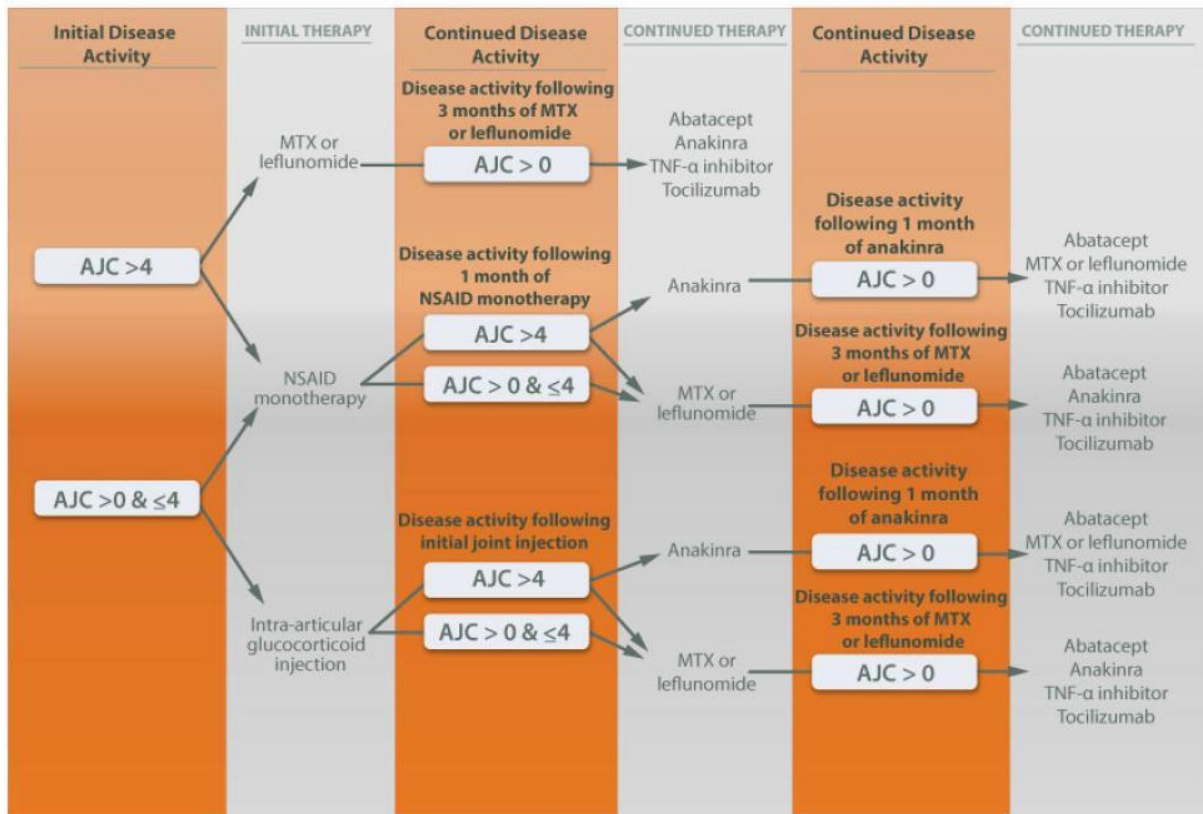


Figure 2. Treatment pathways for patients without active systemic features and with varying degrees of synovitis. The Task Force Panel was asked to rate the appropriateness of therapies based on the total number of active joints ( $\leq 4$  or  $>4$ ). Children may qualify for  $>1$  pathway, in which case it is left to the provider's discretion to choose the path they feel is most appropriate based upon specific patient characteristics and/or patient and family preferences. Steps in the progression of therapy can be additive or sequential, except that therapies with a biologic agent are sequential (combination therapy with a biologic agent is not endorsed). AJC = active joint count; MTX = methotrexate; NSAID = nonsteroidal antiinflammatory drug; IV = intravenous; TNF $\alpha$  = tumor necrosis factor  $\alpha$ .

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512



**Addyi (flibanserin)<sup>®</sup>**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

**COVERAGE CRITERIA**

Addyi will be covered with prior authorization for Commercial and Exchange members when the following criteria are met:

- The patient is a premenopausal female 18 years of age or older.

**AND**

- Patient has been receiving at least an 8 week supply of this medication as a paid claim through a pharmacy or medical benefit (excluding the use of samples or vouchers/coupons) AND has reported symptom improvement.

**AND**

- The patient has not developed any medical or psychiatric conditions or started drug therapy known to cause or contribute to HSDD since starting treatment with Addyi.

**OR**

- The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) that is appropriately documented (i.e., evaluated by a complete clinical assessment, using DSM-4, interviews/questionnaires).

**AND**

- HSDD is NOT caused by a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.

**AND**

- The patient does NOT have any of the following: alcohol use, concomitant use of Addyi with moderate or strong CYP3A4 inhibitors, hepatic impairment.

**REFERENCES**

1. Addyi [package insert]. Raleigh, NC: Sprout Pharmaceuticals Inc; August 2015.
2. Thorp J, Simon J, Dattani D, et al. Treatment of Hypoactive Sexual Desire Disorder in premenopausal women: efficacy of flibanserin in the DAISY study. [J Sex Med.](#) 2012 Mar;9(3):793-804.
3. DeRogatis L, Komer L, Katz M, et al. Treatment of Hypoactive Sexual Desire Disorder in premenopausal women: efficacy of flibanserin in the VIOLET study. [J Sex Med.](#) 2012 Apr;9(4):1074-85.
4. Katz M, DeRogatis L, Ackerman R, Hedges P, et al. Efficacy of flibanserin in women with Hypoactive Sexual Desire Disorder: results from the BEGONIA trial. [J Sex Med.](#) 2013 Jul;10(7):1807-15.
5. American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorder, Fourth Edition, Text Revision. Washington DC: American Psychiatric Association; 2000.
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Reviewed: 02/2016





## **Amevive<sup>®</sup> (alefacept) Prior Authorization Criteria Drug Protocol Management**

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### **Amevive<sup>®</sup> (alefacept)**

#### **How do I obtain a prior authorization for Amevive<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

#### **Criteria for coverage (initial authorization):**

- A. Patient is over 18 years old.
- B. A diagnosis of moderate to severe plaque psoriasis.
- C. Patient is a new NHP member and has been started and stabilized on Amevive<sup>®</sup>,  
**or**
- D. Documentation of moderate to severe plaque psoriasis with body surface area affected (BSA) >10% and /or has involvement of the palms, soles, head and neck, or genitalia, **and**
- E. Documentation of a contraindication, adverse drug reaction, or inadequate response to  $\geq 2$  conventional therapies from the following 3 modalities:
  - **Topical agents:** emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene (trial or contraindication to at least two different agents).
  - **Systemic agents:** methotrexate, sulfasalazine, cyclosporine, tacrolimus, acitretin, mycophenolate mofetil.
  - **Phototherapy:** ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB).**and**
- F. Documentation that baseline CD4+ T lymphocyte count is > 250 cells/ $\mu$ L.

#### **Criteria for coverage (recertification authorization):**

- A. Psoriasis is less than "clear" or shows improvement per physician assessment, **and**
- B. CD4+ T lymphocyte count is  $\geq 250$  cells/ $\mu$ L, **and**
- C. There is a minimum of 12-weeks between the two courses of treatment.

**Treatment beyond two courses has not been established.**

#### **Recommended dose:**

15mg IM once weekly for 12 weeks.



**Ampyra<sup>®</sup> (dalfampridine)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Ampyra<sup>®</sup> (dalfampridine)**

**How do I obtain a prior authorization for Amypra<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Criteria for coverage (initial authorization):**

**Approval Diagnosis:**

- Multiple Sclerosis (MS) with documented evidence of walking disability (see approval criteria)

**Initial Approval Criteria:**

- The member is  $\geq 18$  years of age  
**AND**
- The member has a diagnosis of MS  
**AND**
- The prescribing physician is a neurologist or MS specialist  
**AND**
- The member has a baseline Timed 25-foot Walk test (T25ftWT) with a time range of 8 to 45 seconds  
(Note: walking aids are acceptable; however non-ambulatory patients will not be eligible for approval)
- All other indications will be evaluated on a case-by case basis, including requests for members < 18 years of age. In addition, new members to the plan lacking the above parameters will be reviewed on a case-by-case basis by NHP directly.

**Initial authorizations:** may be issued for up to 3 months. The quantity prescribed must not exceed 60 tablets per 30 days & a maximum 30-day supply per fill.

**Recertification Criteria:**

- Improvement per physician assessment as well as documentation of the following parameters:
  - Stable walking speed without worsening of ambulation
  - At least a 20% improvement in the T25ftWT from baseline
- Reauthorizations may be granted for up to 12 months. The quantity prescribed must not exceed 60 tablets per 30 days & a maximum 30-day supply per fill.

### **Recommended Dosing:**

## Multiple sclerosis:

Adult Dose	Pediatric Dose
<p data-bbox="248 249 604 277"><u>Walking improvement in MS:</u></p> <p data-bbox="248 445 852 512">Extended-release oral tablet: 10 mg BID, taken approximately 12 hours apart, with or without food.</p> <p data-bbox="248 615 886 640">Note: 10 mg BID is the maximum recommended dose.</p> <p data-bbox="248 749 880 844">No additional benefit has been demonstrated at higher doses; however adverse events are increased at higher doses.</p>	<p data-bbox="971 249 1497 310">Safety and efficacy in patients under the age of 18 have not been established.</p>

### Background:

Ampyra® (dalfampridine extended-release; previously known as fampridine-SR) is approved by the FDA as a treatment to improve walking in patients with multiple sclerosis (MS), as demonstrated by an increase in walking speed. According to the manufacturer, dalfampridine can be used alone or with other MS therapies, including disease modifying therapies (DMTs). It should be noted; however, that dalfampridine is not a DMT and is intended to be used for symptomatic relief. Dalfampridine is a broad spectrum potassium channel blocker. However, the exact mechanism by which dalfampridine exerts its therapeutic effect remains unknown. In animal studies, dalfampridine was shown to increase conduction of action potentials in demyelinated axons through the inhibition of potassium channels.

Currently dalfampridine is the only FDA-approved therapy that addresses walking impairment in MS patients and was also the first oral therapy approved for the treatment of MS. Dalfampridine may be used in combination with DMTs including: Avonex® (interferon beta 1a), Betaseron®/Extavia® (interferon beta 1b), Copaxone® (glatiramer acetate), Novantrone® (mitoxantrone), Rebif® (interferon beta 1a), Tysabri® (natalizumab), etc., all of which are administered by intramuscular or subcutaneous injection. Because dalfampridine is a tablet for oral administration, it may represent a more convenient option in addition to currently approved choices. Dalfampridine tablets should only be taken whole and should not be divided, crushed, chewed, or dissolved.

The use of dalfampridine is associated with an increased risk of seizure; therefore, use its use in patients with a history of seizures or evidence of epileptiform activity on an electroencephalogram is contraindicated. Dalfampridine is also contraindicated in patients with moderate to severe renal impairment ( $\leq 50$  ml/min) due to the need of dose adjustment and the absence of a commercially available strength below 10 mg. In addition, dalfampridine is contraindicated in the presence of a known hypersensitivity to 4-aminopyridine. There is also evidence indicating that dalfampridine therapy may activate latent trigeminal neuralgia when used in the treatment of multiple sclerosis; therefore close monitoring and counseling is advised.



## References:

- 1) Ampyra® [package insert]. Hawthorne (NY): Acorda Therapeutics, Inc.; 2014 Jan.
- 2) Acorda therapeutics announces availability of Ampyra™ (dalfampridine) [press release on the Internet]. Hawthorne (NY): Acorda Therapeutics; 2010 Mar 1. Available from: <http://phoenix.corporate-ir.net/phoenix.zhtml?c=194451&p=irol-newsArticle&ID=1396678&highlight=>
- 3) Acorda therapeutics announces FDA approval of Ampyra™ (dalfampridine) to improve walking in people with multiple sclerosis – demonstrated by increases in walking speed) [press release on the Internet]. Hawthorne (NY): Acorda Therapeutics; 2010 Jan 22. Available from: <http://phoenix.corporate-ir.net/phoenix.zhtml?c=194451&p=irol-newsArticle&ID=1378105&highlight=>
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- 8) Ruck T, Bittner S, Simon OJ, Gobel K, Wiendl H, Schilling M, et al. Long-term effects of dalfampridine in patients with multiple sclerosis. *Journal of the Neurological Sciences*. 2014;337(1-2):18-24.



**Botox<sup>®</sup> (botulinum toxin type A)**  
**Myobloc<sup>®</sup> (botulinum toxin type B)**  
**Dysport<sup>®</sup> (abobotulinum toxin A)**  
**Xeomin<sup>®</sup> (incobotulinumtoxin A)**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

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**Botox<sup>®</sup>, Myobloc<sup>®</sup>, Dysport<sup>®</sup> and Xeomin<sup>®</sup> are specialty products; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Botox<sup>®</sup>, Myobloc<sup>®</sup>, Dysport<sup>®</sup> or Xeomin<sup>®</sup>?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Criteria for coverage of Botox<sup>®</sup>:**

Approval for Botox<sup>®</sup> will be granted for the following conditions:

1. Achalasia
  - a. Esophageal achalasia
  - b. Internal anal sphincter (IAS) achalasia
2. Anal Fissure
3. Blepharospasm ( $\geq 12$  years of age)\*;(adult patients)<sup>§</sup>
  - a. Seventh nerve palsy
  - b. Benign essential blepharospasm
4. Cerebral Palsy
  - a. Equinus foot deformity
5. Chronic facial pain associated with temporomandibular dysfunction
6. Dystonia
  - a. Cervical dystonia\*<sup>\*,^,¶,§</sup>
  - b. Writer's cramp
7. Esotropia
8. Exotropia
9. Facial Myokymia
10. Focal hypertonia (lower limb)
11. Hemifacial spasm
12. Hertwig-Magendie sign
13. Contracture in Duchenne muscular dystrophy
14. Axillary Hyperhidrosis, severe\* - (see below criteria)<sup>†</sup>
15. Salivary hypersecretion
  - a. Drooling in Parkinson's disease
  - b. Salivary fistula
16. Strabismus\* ( $\geq 12$  years of age)
17. Tremor
  - a. Essential hand tremor
  - b. Essential voice tremor.



18. Spasmodic torticollis\*
19. Upper limb spasticity in adult patients to decrease the severity of increased muscle tone in elbow flexors, wrist flexors, and finger flexors\*
20. Chronic pain and pelvic floor spasms in women
21. Migraine prophylaxis, chronic\* (see criteria below)
22. Urinary incontinence due to detrusor over-activity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)]\* (see criteria below)
23. Overactive bladder\* (see criteria below)

\* FDA labeled indication (Botox®)

^ FDA labeled indication (Myobloc®)

¶ FDA labeled indication (Dysport®)

§ FDA labeled indication (Xeomin®)

†Reviewed by NHP

**All other requests will be reviewed on a case by case basis. Risk-benefit assessment should precede any decision for use in unlabeled indications as well as establishing that the patient is unresponsive to conventional treatment options.**

### **Axillary Hyperhidrosis**<sup>†</sup>

This is a rare, genetically-based condition that can be quite disturbing; apparent peak incidence during adolescence. Treatment with SQ injections of botulinum toxin has proven efficacious and can result in long-term remission.

We would expect infrequent requests for this therapy. We would be prepared to approve requests for this therapy under the following conditions:

- Treatment is provided by a network contracted dermatologist
- A letter of medical necessity from this provider is needed.
- The patient should have failed an adequate trial of topical therapy.
- Once therapy is initially approved, recurrent treatment with Botox® will only be authorized for the member at a minimal interval of every 3 to 4 months. Subsequent requests also require a letter of medical necessity and clinical review.

### **Chronic Migraine Prophylaxis**

Botox® for the prophylaxis of chronic migraines\* will be authorized when the following criteria have been met:

Note: \* all non- migraine related headaches (e.g., tension headache, cluster headache, etc.) are excluded from coverage.

1. The prescriber is a neurologist or headache specialist or the prescription is being written for the member in consultation with a neurologist or headache specialist
2. The member is  $\geq 18$  years of age
3. The member has been experiencing at least 15 migraine headaches per month with a duration of at least 4 hours a day or longer
4. The member has had an adequate trial of at least THREE (3) different prophylactic migraine medications each with different mechanisms of action (a total of 3 required trials) that have each been tried for at least 60 days in duration within the past 3 years. All three trials must be from Level A or Level B categories within the American Academy of Neurology guidelines (See table 1 below). Note: triptans will not be considered as 'prophylactic options.'

Acceptable trials include:

1. Antiepileptic agents: divalproex sodium, valproate
2. Antiepileptic agents: topiramate
3. Beta-blockers: metoprolol, propranolol, timolol, atenolol, or nadolol



4. Antidepressants: amitriptyline
5. Antidepressants: venlafaxine

Initial requests will be approved for up to 200 units every 3 months for 2 treatments only. Recertification requests may be approved for every 3-month dosing for the requested duration up to a 12-month period when documentation of improvement via physician assessment is submitted indicating evidence of effectiveness, including the following:

- a. A decrease in the frequency of migraine headaches (i.e., the number of headaches per month)
- b. A decrease in the severity of migraine headaches

### **Urinary Incontinence**

Botox<sup>®</sup> is indicated for the treatment of urinary incontinence due to detrusor over-activity associated with a neurologic condition (e.g., Spinal cord injury, MS, etc.) in adults who have an inadequate response to or are intolerant of an anticholinergic medication. Requests for coverage of Botox<sup>®</sup> for this indication will be authorized when the following criteria have been met:

1. The member is  $\geq 18$  years of age
2. The member has a neurological condition resulting in urinary incontinence due to detrusor muscle activity
3. The member has had an adequate trial of at least one (1) long-acting urinary antispasmodic

The recommended dose is 200 units per treatment and should not be exceeded. Patients may be considered for re-treatment when the clinical effects diminish [median time to qualifying for re-treatment in the double-blind, placebo-controlled clinical studies with Botox<sup>®</sup> 200 units was 295-337 days (42-48 weeks)]. Re-treatment should be at an interval no sooner than 12 weeks from the prior bladder injection.

### **Overactive bladder**

Botox<sup>®</sup> is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults who have inadequately responded to or are intolerant of anticholinergic agents.

Requests for Botox<sup>®</sup> for this indication will be authorized when the following criteria have been met:

1. The member is  $\geq 18$  years of age
2. The member has a diagnosis of overactive bladder/urinary incontinence
3. The member has had an adequate trial of at least two (2) long-acting urinary antispasmodic

Note: The recommended dose is 100 Units; which is also the max recommended dose. The recommended dilution is 100 Units/10 mL with 0.9% non-preserved saline solution.

### **Multiple Sclerosis-related tremor/spasticity (upper limbs)**

Botox<sup>®</sup> for upper limb tremor/spasticity related to MS will be authorized when the following criteria have been met:

1. The tremor/spasticity is a result of the multiple sclerosis condition
2. The member has had an adequate trial of at least one (1) oral agent to treat the condition with a documented side effect, allergy, inadequate response, or treatment failure. These agents may include: Baclofen, tizanidine, dantrolene, diazepam, clonazepam, gabapentin, etc.

(Note: phenol injections will also be considered as an appropriate trial for more severe spasticity).



#### **Criteria for coverage of Dysport®**

Approval for Dysport® will be granted for the following conditions:

1. Patient has failed treatment or has developed resistance to botulinum toxin type A (Botox®), **AND**
2. Patient has not had a botulinum toxin type A (Botox®) injection within the last 4 months; **AND**
3. Patient is greater than 18 years old

#### **Criteria for coverage of Myobloc®:**

Approval for Myobloc® will be granted for the following conditions:

1. Patient has failed treatment or has developed resistance to botulinum toxin type A (Botox®), **AND**
2. Patient has not had a botulinum toxin type A (Botox®) injection within the last 4 months, **AND**
3. Patient is greater than 18 years old.

#### **Criteria for coverage of Xeomin®‡**

Approval for **Xeomin®‡** will be granted for the following conditions:

1. Patient has failed treatment or has developed resistance to botulinum toxin type A (Botox®), **AND**
2. Patient has not had a botulinum toxin type A (Botox®) injection within the last 4 months, **AND**
3. Patient is greater than 18 years old.

#### **EXCLUSIONS:**

**Botox®, Myobloc®, Dysport®, & Xeomin® will NOT be covered for cosmetic reasons including but not limited to the following:**

1. Facial rhytides
2. Frown lines
3. Glabellar wrinkling
4. Horizontal neck rhytids
5. Hyperfunctional facial lines
6. Mid and lower face and neck rejuvenation
7. Platysmal bands
8. Rejuvenation of the periorbital region
9. Lateral canthal lines (Crow's feet)

**Coverage of Botox® Cosmetic is not a covered benefit.**

**Coverage of Dysport 300 units [abobotulinum toxin A (glabellar lines)] is not a covered benefit.**



**Brovana<sup>®</sup> (arformoterol) and Perforomist<sup>®</sup> (formoterol)**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

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**Brovana<sup>®</sup> (arformoterol) & Perforomist<sup>®</sup> (formoterol)**

- **Quantity limit of #60 vials per 30 days if approved.**

**How do I obtain a prior authorization for Brovana<sup>®</sup> or Perforomist<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approval Criteria**

Requests for arformoterol (Brovana<sup>®</sup>) and formoterol (Perforomist<sup>®</sup>) will be approved for members who meet any of the following criteria:

1. The patient has a diagnosis of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; **AND**
2. The patient is unable to use a non-nebulized long-acting beta-agonist\* due to a physical limitation;

**OR**

3. The patient has had a documented treatment failure with two (2) different non-nebulized long-acting beta-agonists (i.e. salmeterol, formoterol, indacaterol, vilanterol etc.)\*

**Note:** Like other long-acting beta-agonists, these agents carry a black box warning indicating a potential increase in the risk of asthma-related death.

**FDA Approved Indications**

Indicated for the long-term, twice daily (morning and evening), nebulized maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

\* Long acting beta-agonists: Advair<sup>®</sup> (salmeterol/fluticasone), Foradil<sup>®</sup> (formoterol), Serevent<sup>®</sup> (salmeterol), Symbicort<sup>®</sup> (budesonide/formoterol), Dulera<sup>®</sup> (mometasone/formoterol), Arcapta<sup>™</sup> Neohaler<sup>™</sup> (indacaterol), Breo<sup>®</sup> Ellipta<sup>®</sup> (fluticasone furoate/vilanterol), Anoro<sup>™</sup> Ellipta<sup>®</sup> (umeclidinium/vilanterol), etc.

**References**

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3. Micromedex<sup>®</sup> Healthcare Series, (electronic version). Thomson Micromedex, Greenwood Village, CO, USA. Available at: <http://www.thomsonhc.com>
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5. Hanrahan JP, Sahn SA, Busse W, Schiarappa K, Baumgarner RA, for the Arformoterol COPD Study Group. Efficacy of nebulized arformoterol, a long-acting beta2-adrenergic bronchodilator, in patients with chronic obstructive pulmonary disease: results from two pooled phase III trials. Poster presented at: Annual European Respiratory Society (ERS); September 2-9<sup>th</sup>, 2006; Munich, Germany.
6. Hanrahan JP, Kerwin EM, Cheng H, Drogan DR, Baumgarner RA, for the Arformoterol COPD Study Group. Nebulized arformoterol, a long-acting beta2-adrenergic bronchodilator, in COPD: safety results from two pooled phase III trials. Poster presented at: Annual European Respiratory Society (ERS); September 2-9<sup>th</sup>, 2006; Munich, Germany.
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## **Carbaglu (carglumic acid) Prior Authorization Criteria**

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### **How do I obtain a prior authorization for Carbaglu®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

### **Approval Diagnosis:**

- Hyperammonemia due to the N-acetylglutamate synthetase (NAGS) deficiency

Note: All other indications will be evaluated on a case-by case basis.

### **Approval Criteria:**

- Diagnosis is hyperammonemia due to the N-acetylglutamate synthetase (NAGS) deficiency
- AND**
- The medication is prescribed by or in consultation with a prescriber who specializes in metabolic disorders

**Initial authorizations:** may be issued for duration of treatment requested up to 12 months

- Dispensing is limited to Specialty Pharmacy

### **Recertification Criteria:**

- Improvement per physician assessment/evaluation and documentation of improved and/or normalized blood ammonia levels for age.

### **Recommended Dosing:**

Hyperammonemia (adult & Pediatric dosing):

Initial: 100 to 250 mg/kg/day.

Note: tablets should not be swallowed whole or crushed. Please refer to the prescribing information for adult and pediatric oral administration recommendations as well as nasogastric tube administration directions.

Maintenance: dose titrated to the normal plasma ammonia level for age (generally less than 100 mg/kg/day); total daily dose should be divided into 2 to 4 doses and rounded to the nearest 100 mg.

### **Pharmacist's Notes:**

- Any episode of acute symptomatic hyperammonemia should be treated as a life-threatening emergency & treatment may require hemodialysis in some instances.
- The management of hyperammonemia due to NAGS deficiency should be done in coordination with medical personnel experienced in metabolic disorders.
- Plasma ammonia levels should also be maintained within normal range for age through individual dose adjustment.
- During acute hyperammonemic episodes, protein restrictions and hyper-caloric intake is recommended to block ammonia-generating catabolic pathways. Protein intake can subsequently be increased when ammonia levels have normalized.

### **References:**

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  2. Carbaglu [press release on the Internet]. Paris (France): Orphan Europe SARL; 2009 Jul 15 [cited 2011 Jun 4]. Available from: <http://www.orphan-europe.com/Data/ModuleGestionDeContenu/04-Products/Carbaglu/30.asp>.
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- Last reviewed: 6/27/16



**Bunavail® (buprenorphine/naloxone)  
Prior Authorization Criteria Drug  
Protocol Management**

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**Bunavail® (buprenorphine/naloxone) buccal film**

- **Quantity Limit**
  - 2.1 mg/0.3 mg strength: 30 units per 30 days
  - 4.2 mg/0.7 mg strength: 90 units per 30 days
  - 6.3 mg/1.0 mg strength: 30 units per 30 days

**How do I obtain a prior authorization for Bunavail®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Treatment of opioid dependence

**Approval Criteria**

- Patient has a diagnosis of opioid dependence **AND**
- Patient has experienced a documented inadequate response or intolerance, such as an allergic reaction, with the generic buprenorphine/naloxone (*compare to Suboxone®*) tablets **AND**
- Patient has experienced a documented inadequate response or intolerance, such as an allergic reaction, with the Zubsolv® (buprenorphine/naloxone) sublingual tablets

Initial approvals may be issued for a duration of 6 months.

**Recertification Criteria**

- Documented of medication effectiveness and treatment plan.

Reauthorizations may be granted for up to 6 months.

**References**

- Zubsolv [package insert]. Wilmington (NC): Orexo US, Inc.; 2014 Dec.
- Bunavail® [package insert]. Raleigh (NC): BioDelivery Sciences International, Inc.; 2014 Jun.
- Biodelivery Sciences receives FDA approval for Bunavail® (buprenorphine and naloxone) buccal film for the maintenance treatment of opioid dependence [press release]. Raleigh (NC): BioDelivery Sciences International, Inc.; 2014 Jun 9. Available at: [http://bdsi.investorroom.com/media\\_pr](http://bdsi.investorroom.com/media_pr)



**Cimzia® (certolizumab)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Cimzia® (certolizumab) is a specialty product; dispensing is available via NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Cimzia®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Crohn's disease
- Moderately to severely active rheumatoid arthritis (RA)
- Psoriatic arthritis
- Ankylosing spondylitis

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Cimzia® for an approvable indication

**OR**

- Patient is  $\geq 18$  years of age **AND**
- Patient has a diagnosis of Crohn's disease **AND**
- Patient experienced an inadequate response or intolerance to treatment with conventional immunomodulators\* such as methotrexate, azathioprine, 6-mercaptopurine, etc.

**OR**

- Patient is  $\geq 18$  years of age **AND**
- Patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA), psoriatic arthritis, or ankylosing spondylitis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD\*\*, if methotrexate is contraindicated) \*\*†

\* Conventional immunomodulators include methotrexate, cyclosporine, azathioprine, tacrolimus, and 6-mercaptopurine

\*\* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

\*\*† Methotrexate/DMARD trial requirement may be overridden for patients with documented axial disease in ankylosing spondylitis or psoriatic arthritis whose condition is not adequately controlled with NSAIDs AND for RA patients with documented high disease activity (advanced disease) with features of a poor prognosis (i.e., functional limitations, extra-articular disease, positive rheumatoid factor, or anti-cyclic citrullinated peptide antibodies, & bony erosions by radiograph)

Initial approvals may be issued for up to 6 months.

**Reauthorization Criteria**

- Improvement per physician assessment of overall disease activity

Reauthorizations may be granted for up to 6 months.

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- U.S. Food and Drug Administration. FDA News: FDA approves Cimzia® to treat Crohn's Disease [webpage on the internet]. Rockville (MD); U.S. Department of Health and Human Services: 2008. Available from: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01821.html>
- Cimzia® [package insert]. Smyrna (GA): UCB, Inc; 2013 Oct.
- UCB's Cimzia® (certolizumab pegol) approved by the U.S. FDA for adult patients suffering from moderate to severe rheumatoid arthritis. Press Release. 2009 May 14. Available at: <http://www.ucb.com/media-room/newsdetail/?det=1314787&select-year=&select-archive=>. Accessed: 15 Jan 2009.
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- Cimzia® (certolizumab pegol) approved by the U.S. FDA for treatment of adult patients with active psoriatic arthritis [press release on the internet]. UCB Pharma. 2013 September 20. Available at: <http://www.ucb.presscentre.com/content/default.aspx?NewsAreaID=2>
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- Gottlieb A, Korman NJ, Gordon KB, Feldman SR, Lebwohl M, Koo JYM, et al. Guidelines for care for the management of psoriasis and psoriatic arthritis. *J Am Acad Derm*. 2008;58:851-64.

Last reviewed/updated: 4/6/2015



**Cosentyx® (secukinumab)  
Prior Authorization Criteria  
Drug Protocol Management**

**Approvable Diagnoses**

- Psoriatic arthritis
- Moderate to severe chronic plaque psoriasis

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Cosentyx® for an approvable indication
- OR**
- Patient is  $\geq 18$  years if age **AND**
  - Patient has a diagnosis of psoriatic arthritis **AND**
  - Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD<sup>†</sup>, if methotrexate is contraindicated)<sup>\*†</sup> **AND**
  - Patient has experienced an inadequate response or intolerance to treatment with a tumor necrosis factor (TNF) blocking agent (unless medical rationale is presented as to why treatment with a TNF blocking agent is contraindicated) or
  - Patient is  $\geq 18$  years if age **AND**
  - Patient has a diagnosis of moderate to severe chronic plaque psoriasis affecting  $\geq 10\%$  body surface area **AND**
  - Patient has experienced an inadequate response or intolerance to at least **one (1)** agent from at least **two (2)** of the following **three (3)** categories:
    - **Topical agents:** emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene
    - **Systemic agents:** methotrexate, sulfasalazine, cyclosporine, tacrolimus, acitretin, mycophenolate mofetil, azathioprine, hydroxyurea, etc.
    - **Phototherapy:** ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB), etc.

<sup>†</sup> Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

<sup>\*†</sup> Methotrexate/DMARD trial requirement may be overridden for patients with documented axial disease whose condition is not adequately controlled with NSAIDs

**Reauthorization Criteria**

- Improvement per physician assessment of overall disease activity





## **Compound Drug Products Prior Authorization Criteria**

### **COVERAGE CRITERIA**

Compounded drug products will be covered with prior authorization when the following criteria are met:

- Coverage is provided when the patient has an active authorization for the requested compound with documentation that could be provided to Neighborhood Health Plan upon request
  - Coverage is provided when the route of administration of the compound is the same as the FDA-approved or compendial supported route of administration for each active ingredient
  - Coverage is provided when the dosing is within guidelines for each active ingredient
  - Coverage is provided in situations where each of the active ingredients in the compound are FDA-approved drugs
  - Coverage is provided when each of the active ingredients in the compound is used for an indication that is FDA-approved
- AND**
- There is a current supply shortage of the commercial product
- OR**
- The patient has a medical need for a dosage form or dosage strength that is not commercially available
- OR**
- The patient had a trial and intolerance to or contraindication to the commercially available product (e.g., allergen/preservative/dye-free, palatable for pediatrics, adverse effects to binders/fillers/other inactive ingredients)
- OR**
- The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness
- AND**
- Coverage is not provided for compounds applied topically (e.g., cream, gels, lotions, ointments) that contain bulk powders OR any ingredient that is not FDA approved for topical use OR any of the following ingredients:
    - Amitriptyline
    - Baclofen
    - Cholestyramine
    - Cyclobenzaprine
    - Dexamethasone (except ophthalmic solution)
    - Flurbiprofen (except ophthalmic solution)
    - Fluticasone propionate
    - Gabapentin
    - Hyaluronate (except ophthalmic solution)
    - Itraconazole
    - Ketamine
    - Ketoprofen
    - Ketorolac (except ophthalmic solution)
    - Lamotrigine
    - Meloxicam

- Penlac
  - Sumatriptan
  - Tramadol
- Coverage is not provided in situations where the compound is intended for scar diminishing, cosmetic use, anti-aging, OR contains any of the following ingredients:
    - Coenzyme Q10 (Ubiquinol)
    - Collagenase (Santyl)
    - Naltrexone
    - Resveratrol
  - Coverage is provided for additional fills of the compounded drug if patient needs more than 1 fill per month (necessity may include continuation of antibiotic therapy, stability of water-containing formulation is less than a month, dose adjustment)
- OR**
- Coverage is provided for total parenteral nutrition (TPN) OR for antibiotics or anti-infectives for injectable use

## **REFERENCES**

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Last reviewed/updated: 5/27/16



**Daliresp<sup>®</sup> (roflumilast) Prior  
Authorization Criteria Drug  
Protocol Management**

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**Daliresp<sup>®</sup> (roflumilast)**

- **Quantity Limit: 30 tablets per 30 days**

**How do I obtain a prior authorization for Daliresp<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis and a history of exacerbations

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Daliresp<sup>®</sup> for the approvable indication  

**OR**
- Patient has a diagnosis of severe COPD associated with chronic bronchitis and a history of exacerbations **AND**
- Patient has had a documented side effect, allergy, or treatment failure with at least one orally-inhaled corticosteroid<sup>†</sup> **AND**
- Patient has had a documented side effect, allergy, or treatment failure with at least one orally inhaled, long-acting anticholinergic **AND**  
Patient has had a documented side effect, allergy, or treatment failure with at least one orally-inhaled, long-acting beta agonist **AND**
- Patient will be using the requested medication in combination with at least one orally-inhaled, long-acting bronchodilator

Initial approvals may be issued for up to 12 months. Reauthorizations may be granted for up to an additional 6 months.

**Reauthorization Criteria**

- Improvement per physician assessment/evaluation of overall disease activity within the previous 6 months from time of recertification request

Reauthorizations may be granted for up to 36 months.

**References**

- Daliresp<sup>®</sup> [package insert]. St. Louis (MO): Forest Pharmaceuticals, Inc.: 2014 Sep.
- Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease; Updated 2015. 2015 [cited 20 May 2015]. Available at: <http://www.goldcopd.org/Guidelines/guidelines-resources.html>
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Last reviewed/updated: 6/27/2016



**Diclegis® (doxylamine succinate and pyridoxine hydrochloride)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Diclegis® (doxylamine succinate and pyridoxine hydrochloride)**

- **Quantity Limit: 120 tablets per 30 days**

**How do I obtain a prior authorization for Diclegis®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management

**Approval Criteria**

- The patient is new to NHP and has been stabilized on Diclegis® for the approvable indication  
**OR**
- The patient has a diagnosis of nausea and vomiting associated with an active pregnancy **AND**
- The patient has had an inadequate response to conservative measures including, but not limited to, dietary changes and the use of ginger, acupuncture, mint, licorice, etc. **AND**
- The patient has had an inadequate response to generic pyridoxine (vitamin B<sub>6</sub>) dosed at 10 to 25 mg 3 to 4 times daily, either as monotherapy or in combination with a product containing doxylamine

**Approval Duration**

- Initial approvals will be for a duration of 4 months. Reauthorizations may be granted for up to an additional 6 months.

**References**

- Diclegis® [prescribing information]. Duchesnay Inc. Bryn Mawr, PA. 2013 Apr.
- Drugs@FDA: FDA Approved Drug Products. FDA, n.d. Web. Accessed 8 Apr. 2013. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails>.
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Last reviewed/updated: 6/8/2015



**Emsam<sup>®</sup> (selegiline) Prior  
Authorization Criteria Drug  
Protocol Management**

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**Emsam<sup>®</sup> (selegiline)**

- **Quantity Limit: 30 patches/30 days**

**How do I obtain a prior authorization for Emsam<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Major Depressive Disorder

**Approval Criteria**

- Patient is  $\geq 12$  years of age **AND**
- The request is from a psychiatrist **AND**
- Patient has had a documented side effect, allergy, or treatment failure with at least 3 different antidepressant agents from 3 different antidepressant classes [e.g. SSRIs, SNRIs, TCAs (including maprotiline), mirtazapine, bupropion, etc.]\* **AND**
- Patient has had a documented side effect, allergy, or treatment failure with an oral monoamine oxidase inhibitor (MAOI)

**OR**

- Patient is  $\geq 12$  years of age **AND**
- The request is from a psychiatrist **AND**
- Patient is unable to tolerate oral medications, including liquid and crushed formulations

Approvals will be for a duration of 3 years (36 months).

\*Note: when switching to or from an MAOI (e.g. Emsam<sup>®</sup>) a washout period is mandatory. In general, a washout period of 2 weeks is sufficient for most drugs without a long half-life (e.g., TCAs, paroxetine, fluvoxamine, venlafaxine, etc.); however, drugs with a long half-life (e.g., fluoxetine) require a minimum of 5 to 6 weeks for a washout period.

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Last reviewed/updated: 1/12/15





**Enbrel® (etanercept) Prior  
Authorization Criteria Drug  
Protocol Management**

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**Enbrel® (etanercept) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Enbrel®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Rheumatoid arthritis (RA)
- Polyarticular juvenile idiopathic arthritis (PJIA)
- Psoriatic arthritis
- Ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Enbrel® for an approvable indication  
**OR**
- Patient has a diagnosis of rheumatoid arthritis, ankylosing spondylitis, or psoriatic arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD\*, if methotrexate is contraindicated) \*†  
**OR**
- Patient is  $\geq 2$  years of age **AND**
- Patient has a diagnosis of polyarticular juvenile idiopathic arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with the recommended initial and continued therapies (please refer to Appendices 1 & 2 below)  
**OR**
- Patient has a diagnosis of moderate to severe chronic plaque psoriasis affecting  $\geq 10\%$  body surface area **AND**
- Patient has experienced an inadequate response or intolerance to at least **one (1)** agent from at least **two (2)** of the following **three (3)** categories:
  - **Topical agents:** emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene
  - **Systemic agents:** methotrexate, sulfasalazine, cyclosporine, tacrolimus, acitretin, mycophenolate mofetil, azathioprine, hydroxyurea, etc.
  - **Phototherapy:** ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB), etc.

\* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

\*† Methotrexate/DMARD trial requirement may be overridden for patients with documented axial disease in ankylosing spondylitis or psoriatic arthritis whose condition is not adequately controlled with NSAIDs AND for RA patients with documented high disease activity (advanced disease) with features of a poor prognosis (i.e., functional limitations, extra-articular disease, positive rheumatoid factor, or anti-cyclic citrullinated peptide antibodies, & bony erosions by radiograph)

Initial approvals may be issued for up to 6 months for all indications except for plaque psoriasis; initial approvals for plaque psoriasis may be issued for up to 3 months.

## Reauthorization Criteria

### All indications except plaque psoriasis

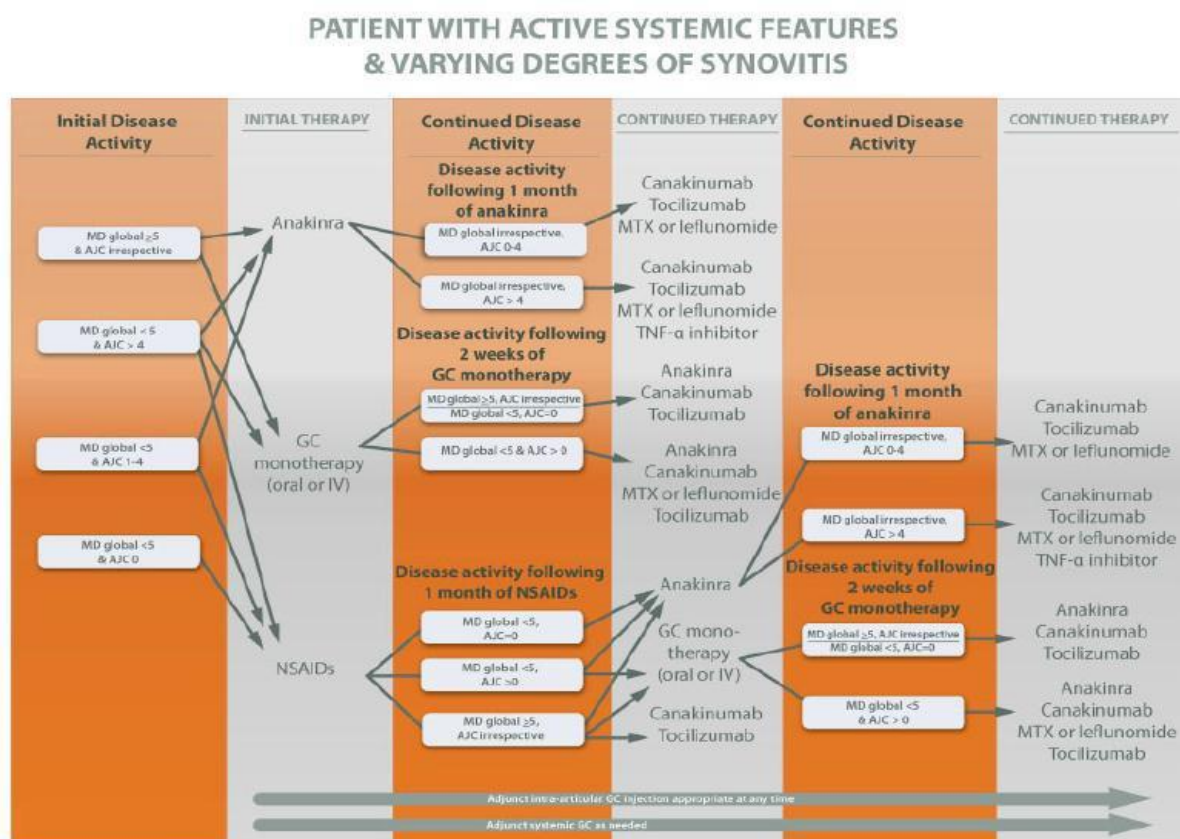
- Improvement per physician assessment of overall disease activity

### Plaque psoriasis

- Disease that is less than clear or responding to treatment per physician assessment

Reauthorizations may be granted for up to 1 year for all indications except plaque psoriasis; reauthorizations for plaque psoriasis may be issued for up to 6 months.

## Appendix 1



**Figure 1.** Treatment pathways for patients with active systemic features and varying degrees of synovitis. The Task Force Panel was asked to consider the treatments among patients with active systemic features and a physician global assessment (MD global) of  $< 5$  or  $\geq 5$  on a 10-point numerical rating scale (0–10 visual analog scale, where 0 = no disease activity and 10 = the most severe) and by active joint count (AJC; 0 joints, 1–4 joints, or  $> 4$  joints). If a recommendation is noted to be irrespective of the AJC or MD global, the recommendation was for children with an AJC  $\geq 0$  or an MD global  $> 0$ , respectively. Adjunct systemic glucocorticoids (GCs) and/or intraarticular GCs may be added at any point. Children may qualify for  $> 1$  pathway, in which case it is left to the provider's discretion to choose the path they feel is most appropriate based upon specific patient characteristics and/or patient and family preferences. Steps in the progression of therapy can be additive or sequential, except that therapies with a biologic agent are sequential (combination therapy with a biologic agent is not endorsed). The recommendations in this figure are for patients with active systemic features. If the systemic features (but not the arthritis) respond to therapy, then subsequent treatment decisions should be based upon the recommendations in Figure 2. NSAIDs = nonsteroidal antiinflammatory drugs; IV = intravenous; MTX = methotrexate; TNF $\alpha$  = tumor necrosis factor  $\alpha$ .

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512

## Appendix 2

### PATIENT WITHOUT ACTIVE SYSTEMIC FEATURES & VARYING DEGREES OF SYNOVITIS

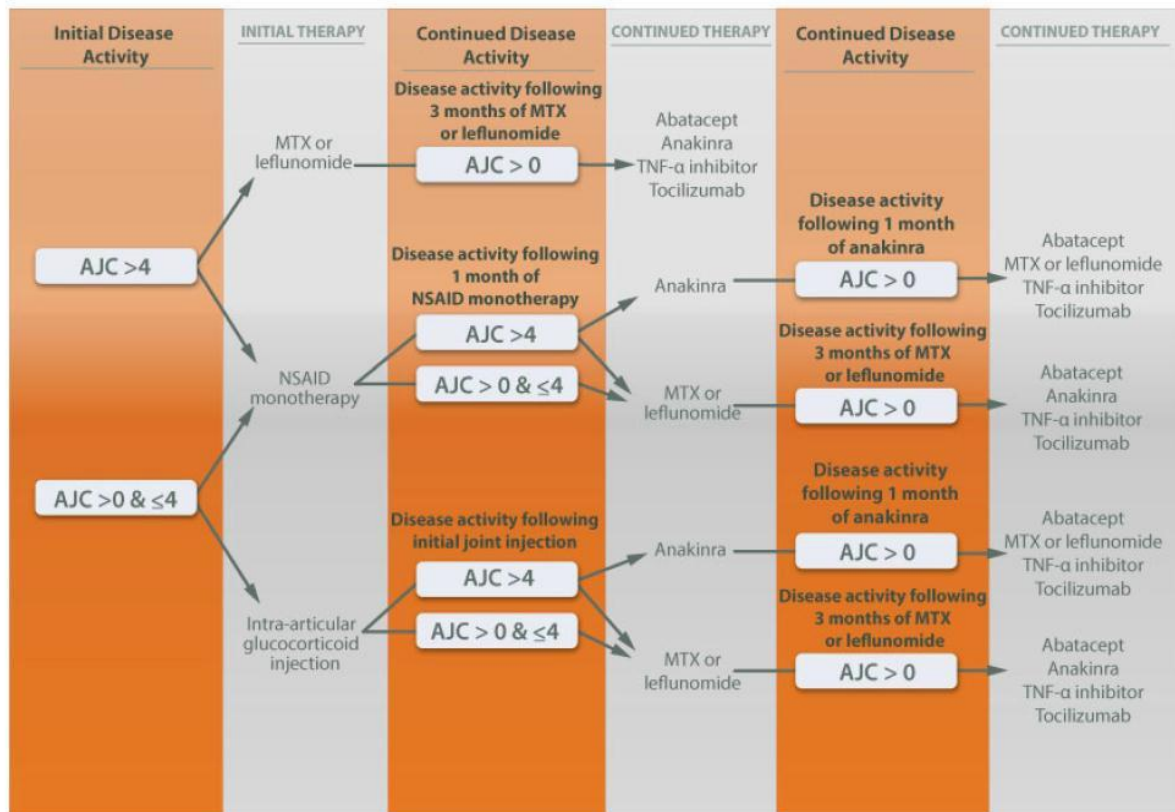


Figure 2. Treatment pathways for patients without active systemic features and with varying degrees of synovitis. The Task Force Panel was asked to rate the appropriateness of therapies based on the total number of active joints ( $\leq 4$  or  $> 4$ ). Children may qualify for  $> 1$  pathway, in which case it is left to the provider's discretion to choose the path they feel is most appropriate based upon specific patient characteristics and/or patient and family preferences. Steps in the progression of therapy can be additive or sequential, except that therapies with a biologic agent are sequential (combination therapy with a biologic agent is not endorsed). AJC = active joint count; MTX = methotrexate; NSAID = nonsteroidal antiinflammatory drug; IV = intravenous; TNF $\alpha$  = tumor necrosis factor  $\alpha$ .

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512

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**Entyvio® (vedolizumab)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Entyvio® (vedolizumab) is a specialty product; dispensing is available at NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 4 vials per 16 weeks applies for initial approvals; reauthorizations are subject to a quantity limit of 6 vials per 48 weeks.**

**How do I obtain a prior authorization for Entyvio®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Crohn's disease
- Ulcerative colitis

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Entyvio® for an approvable indication

**OR**

- Patient is  $\geq 18$  years if age **AND**
- Patient has a diagnosis of Crohn's disease or ulcerative colitis **AND**
- Patient has experienced an inadequate response or intolerance to one or more conventional immunomodulator therapies† **AND**
- Patient has experienced an inadequate response or loss of response with a tumor necrosis factor (TNF) blocking agent approved for the treatment of the respective diagnosis (i.e., Humira® or Cimzia® for Crohn's disease\*; Humira® or Simponi® for ulcerative colitis)\* **AND**
- Patient has experienced an inadequate response with Remicade®\*

† Conventional immunomodulator therapies include methotrexate, cyclosporine, azathioprine, tacrolimus, and 6-mercaptopurine

\* For patients with fistulizing Crohn's disease, the only TNF blocking agent trial required is Remicade®. Initial approvals will be for a duration of 4 months.

**Reauthorization Criteria**

- Patient continues to experience a therapeutic response (as documented by prescriber) to Entyvio® therapy

Reauthorizations will be for a duration of 12 months.

**References**

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Last reviewed/updated: 4/6/15





**Forteo™ (teriparatide) Prior  
Authorization Criteria Drug  
Protocol Management**

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**Forteo™ (teriparatide) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Forteo™?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Glucocorticoid-induced osteoporosis
- Osteoporosis in post-menopausal women
- Osteoporosis in men

**Approval Criteria**

- Patient has a bone mineral density that is more than or equal to 4.0 standard deviations below the mean (e.g. T-score at or below -4.0)

**OR**

- Patient has had a low trauma fracture

**OR**

- Patient has glucocorticoid-induced osteoporosis, is a postmenopausal female with osteoporosis, or is a male with primary or hypogonadal osteoporosis **AND**
- Patient has a bone mineral density that is more than or equal to 2.5 standard deviations below the mean. (e.g. T-score at or below -2.5) **AND**
- Patient has, either,:
  - Previously tried at least one oral bisphosphonate and at least one of the following has occurred: intolerable side-effect, allergy or treatment failure (e.g. new fracture) with consistent bisphosphonate therapy for 1 year **or**
  - Not previously tried an oral bisphosphonate due to a contraindication (e.g. current esophageal stricture or ulcer, GERD, CrCl < 35mL/min, or the inability to stand or sit upright for at least 30 minutes) **AND**
- Patient does **not** have any of the following conditions:
  - A baseline risk of osteosarcoma including: Paget's disease of bone, unexplained elevations of alkaline phosphatase, open epiphyses in pediatric and young adult patients, or prior external beam or implant radiation therapy involving the skeleton
  - Bone metastases
  - A history of skeletal malignancy
  - Hypercalcemia
  - Primary hyperparathyroidism
  - Metabolic bone disease other than osteoporosis

Approvals will be for a maximum of 1 year of therapy.

Note: Medical necessity rationale for teriparatide for indications outside of those approved by the FDA will be evaluated on a case-by-case basis.

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Last reviewed/updated: 1/12/15



## **Fulyzaq<sup>®</sup> (crofelemer) Prior Authorization criteria Drug Protocol Management**

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### **Fulyzaq<sup>®</sup> (crofelemer)**

- **Quantity limit: 60 tablets/30 days**

### **How do I obtain a prior authorization for Fulyzaq<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

### **Approvable Diagnosis**

- Treatment of HIV/AIDS-related diarrhea of non-infectious origin

### **Approval Criteria**

- Patient is  $\geq 18$  years of age **AND**
- Patient has a diagnosis of human immunodeficiency virus (HIV) or acquired immunodeficiency disease (AIDS) and is actively receiving anti-retroviral therapy which has resulted in a non-infectious form of diarrhea **AND**
- Patient has experienced an inadequate response or intolerance to treatment with both loperamide and diphenoxylate/atropine

Initial authorizations will be approved for 12 months.

### **Reauthorization Criteria**

- Patient continues to actively receive anti-retroviral therapy **AND**
- Symptom improvement per physician assessment

Reauthorizations may be granted for up to 12 months.

### **References**

- FDA approves FULYZAQ (crofelemer) 125 mg delayed-release tablets for the symptomatic relief of diarrhea in patients with HIV/AIDS on anti-retroviral therapy (ART). Salix Pharmaceuticals Press Release January 2, 2013. Available at: [http://www.salix.com/news-media/news/index.aspx/fda-approves-fulyzaq-\(crofelemer\)-125-mg-delayed-release-tablets-for-the-symptomatic-relief-of-diarrhea-in-patients-with-hiv-aids-on-anti-retroviral-therapy-art](http://www.salix.com/news-media/news/index.aspx/fda-approves-fulyzaq-(crofelemer)-125-mg-delayed-release-tablets-for-the-symptomatic-relief-of-diarrhea-in-patients-with-hiv-aids-on-anti-retroviral-therapy-art).
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Last reviewed/updated: 4/6/15



**Gilenya<sup>®</sup> (fingolimod) Prior  
Authorization criteria Drug  
Protocol Management**

**Approval Diagnosis:**

- Relapsing forms of Multiple Sclerosis (MS)

**Approval Criteria:**

- The member has a diagnosis of a relapsing form of MS **AND**
  - Patient is a new NHP member and has already been started and stabilized on fingolimod for an approved indication
- OR**
- The member has a diagnosis of a relapsing form of MS **AND**
  - The prescribing physician is a neurologist or MS specialist

**Initial authorizations** - may be issued for up to 12 months.

**Recertification Criteria:**

- Improvement per physician assessment of overall disease activity, including a reduction in clinical exacerbations and/or prevention of worsening of physical disability
  - Reauthorizations may be granted for up to 12 months.

**Recommended Dosing:**

**Relapsing forms of multiple sclerosis:**

<b>Adult Dose</b>	<b>Pediatric Dose</b>
Treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability: <b>One capsule (0.5 mg) orally once daily.</b>	Safety and efficacy have not been established.

**Allowed quantity:**

The quantity prescribed must not exceed 30 capsules per 30 days

Based upon FDA requirements published on May 14, 2012, the following 1<sup>st</sup>-dose monitoring and contraindications were updated within the prescribing information (PI). For further warnings & precautions please refer to the PI.

### First Dose Monitoring:

- Observe all patients for signs and symptoms of bradycardia for at least 6 hours after 1<sup>st</sup> dose with hourly pulse and blood pressure measurement. Obtain ECG prior to dosing and at the end of the observation period.
- Patients who have a heart rate 6-hours post-dose of <45 bpm, the heart rate 6 hours post-dose is at the lowest value post-dose (i.e., suggesting the max pharmacodynamic effect on the heart may not have occurred), and whose ECG 6 hours post-dose shows new onset 2<sup>nd</sup>-degree or higher AV block should be monitored until resolution of the finding. Patients at lowest post-dose heart rate at the end of the observation period should be monitored until heart rate increases.
- In patients experiencing symptomatic bradycardia, begin continuous ECG monitoring until the symptoms have resolved; if pharmacological intervention is required to treat bradycardia, continuous ECG monitoring should continue overnight in a medical facility, and 1<sup>st</sup>-dose monitoring procedures should be repeated for the 2<sup>nd</sup> dose.
- Patients with some preexisting conditions (e.g., ischemic heart disease, history of myocardial infarction, CHF, history of cardiac arrest, cerebrovascular disease, uncontrolled hypertension, history of symptomatic bradycardia, history of recurrent syncope, severe untreated sleep apnea, AV block, sinoatrial heart block) may poorly tolerate the fingolimod-induced bradycardia, or experience serious rhythm disturbances after the first dose. Prior to treatment, these patients should have a cardiac evaluation, and, if treated with fingolimod, should be monitored overnight with continuous ECG in a medical facility after the first dose.
- Patients with prolonged QTc interval at baseline or during the observation period, or taking drugs with known risk of torsades de pointes should be observed overnight with continuous ECG monitoring.

### Re-initiation of Therapy Following Discontinuation:

- If therapy is discontinued for more than 14 days, after the first month of treatment, reintroduction of fingolimod may result in recurrence of the effects on heart rate and AV conduction. First dose monitoring for the initial retreatment dose should apply.
- Within the first 2 weeks of therapy, first dose monitoring is recommended for interruptions of one day or more.
- During weeks 3 or 4, first dose monitoring is recommended for interruptions of more than 7 days.

### Pharmacist Notes:

Fingolimod is contraindicated in the following scenarios:

- Recent (within the last 6 months) occurrence of: MI, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker
- Baseline QTc interval  $\geq 500$  ms
- Treatment with Class Ia or Class III anti-arrhythmic drugs



**Gonadotropins  
Prior Authorization Criteria  
Drug Protocol Management**

**How do I obtain a prior authorization for non-preferred fertility agents?**

- Contact CVS Specialty at (866) 814-5506 for questions.
- Fertility agents are **only** covered for Commercial and Exchange members.
- First-line agents do **not** require prior authorization unless the patient is >45 years of age.
- Medical services must be authorized prior to drug approval.

**First-Line Agents\***

Follistim AQ  
Cetrotide  
Menopur

\*Brand Name: Second tier copay

**Second-Line Agents+**

Gonal- F RFF  
Bravelle  
Ganirelix

+Brand Name: Third tier copay, if approved

**Approval Criteria for Gonal-F RFF and Bravelle:**

1. A trial of Follistim AQ is required unless contraindicated. Documentation of treatment failure related to, inability to tolerate or adverse reaction to Follistim AQ is required.
2. Actively receiving therapy with non-preferred agent.

NOTE: Approval would be for enough medication to complete the current treatment cycle.

**Approval Criteria for Ganirelex:**

3. A trial of Cetrotide is required unless contraindicated. Documentation of treatment failure related to, inability to tolerate or adverse reaction to Cetrotide is required.
4. Actively receiving therapy with non-preferred agent.

NOTE: Approval would be for enough medication to complete the current treatment cycle.

**Authorizations may be issued for up to 12 months.**

**Last reviewed/updated: 4/6/15**



**GRASTEK® (Timothy grass pollen allergen extract)  
Prior Authorization Criteria**

Grastek is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Grastek is approved for use in persons 5 through 65 years of age.

Grastek is not indicated for the immediate relief of allergic symptoms.

**Criteria:**

- The member is new to NHP and has been stabilized on GRASTEK for an approvable indication by a specialist (allergist or immunologist) or under recommendation of a specialist via consult within the previous year

**OR**

- The prescriber is an allergist or immunologist, or the therapy has been recommended by a specialist via consult within the previous year **AND**
- The member is at least 5 years of age with a diagnosis of allergic rhinitis with or without conjunctivitis **AND**
- The member does not have a diagnosis of severe or uncontrolled asthma **AND**
- The member has had a skin test or *in vitro* testing confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen (e.g., grass pollen) and therapy will begin 12 weeks prior to the allergy season **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with at least one non-sedating antihistamine (e.g., loratadine, cetirizine, fexofenadine, etc.) **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with an intranasal corticosteroid **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with an intranasal antihistamine **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with a leukotriene modifier (e.g., montelukast, zafirlukast, etc.) **AND**
- The member will be prescribed and trained to self-administer epinephrine rescue therapy **AND**

The requested quantity does not exceed 30 tablets per 30 days





## **Ragwitek Prior Authorization Criteria Drug Protocol Management**

Ragwitek is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen. Ragwitek is approved for use in persons 18 through 65 years of age. Ragwitek is not indicated for the immediate relief of allergic symptoms.

### **Approval Criteria**

- The member is new to NHP and has been stabilized on RAGWITEK for an approvable indication by a specialist (allergist or immunologist) or under recommendation of a specialist via consult within the previous year

### **OR**

- The prescriber is an allergist or immunologist, or the therapy has been recommended by a specialist via consult within the previous year **AND**
- The member is at least 18 years of age with a diagnosis of allergic rhinitis with or without conjunctivitis **AND**
- The member does not have a diagnosis of severe or uncontrolled asthma **AND**
- The member has had a skin test or *in vitro* testing confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen (e.g., short ragweed pollen) and therapy will begin 12 weeks prior to the allergy season **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with at least one non-sedating antihistamine (e.g., loratadine, cetirizine, fexofenadine, etc.) **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with an intranasal corticosteroid **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with an intranasal antihistamine **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with a leukotriene modifier (e.g., montelukast, zafirlukast, etc.) **AND**
- The member will be prescribed and trained to self-administer epinephrine rescue therapy **AND**
- The requested quantity does not exceed 30 tablets per 30 days

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Last reviewed/updated: 6/9/14



## **Oralair Prior Authorization Criteria Drug Protocol Management**

### **FDA-APPROVED INDICATIONS**

Oralair is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product. Oralair is approved for use in persons 10 through 65 years of age. Oralair is not indicated for the immediate relief of allergy symptoms.

### **CRITERIA**

- The member is new to NHP and has been stabilized on ORALAIR for an approvable indication by a specialist (allergist or immunologist) or under recommendation of a specialist via consult within the previous year

#### **OR**

- The prescriber is an allergist or immunologist, or the therapy has been recommended by a specialist via consult within the previous year **AND**
- The member is at least 10 years of age with a diagnosis of allergic rhinitis with or without conjunctivitis **AND**
- The member does not have a diagnosis of severe or uncontrolled asthma **AND**
- The member has had a skin test or in vitro testing confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen (e.g., grass pollen) and therapy will begin 16 weeks prior to the allergy season **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with at least one non-sedating antihistamine (e.g., loratadine, cetirizine, fexofenadine, etc.) **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with an intranasal corticosteroid **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with an intranasal antihistamine **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with a leukotriene modifier (e.g., montelukast, zafirlukast, etc.) **AND**
- The member will be prescribed and trained to self-administer epinephrine rescue therapy **AND**
- The requested quantity does not exceed 30 tablets per 30 days\*

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Reviewed: 4/25/16 P&T Mtg



**Growth Hormone  
Prior Authorization Criteria  
Drug Protocol Management**

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**All growth hormone products are considered specialty products; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.** Omnitrope<sup>®</sup> (somatropin) and Tev-Tropin<sup>®</sup> (somatropin) are Neighborhood Health Plan's preferred, or first-line, growth hormone products. Requests for coverage of a non-preferred, or second-line, growth hormone product will be considered for patients who have experienced a documented side effect, intolerance, or treatment failure with either Omnitrope<sup>®</sup> or Tev-Tropin<sup>®</sup>.

**Preferred agents**

- ☐ Norditropin
- ☐ Omnitrope

**How do I obtain a prior authorization for growth hormone?**

- ☐ Download a prior authorization fax form & send to (866) 249-6155.
- ☐ Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Children Diagnosed With Acquired Growth Hormone Deficiency:**

- a) *Prescribing:* The requesting prescriber must be a pediatric endocrinologist
- b) *Height:* The patient's baseline height must be < the 3rd percentile (i.e. > 2 standard deviations [SD] below the mean for gender & age, a measure of the degree of short stature)
- c) *Growth velocity:* must be below the 25th percentile for age and gender, unless diagnosed with an abnormality in pubertal development
- d) *Provocative growth hormone testing:* The patient must have a documented growth hormone deficiency as defined by a diminished serum growth hormone response to stimulation testing of <10ng/ml. The results of at least two of the following stimulation tests are required for a diagnosis of growth hormone deficiency: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon

\*For children who meet criteria a, b, and c, coverage of growth hormone on a 12-month trial basis is recommended for those who meet the following criteria:

- 1) Two provocative growth hormone tests must still be documented to show stimulated serum concentrations >10ng/ml
- 2) A pediatric endocrinologist must certify that:
  - a. the child's ability to participate in basic activities of daily living is limited by their short stature (i.e. the degree of growth retardation is considered medically significant by the physician)
  - b. the child has a condition for which growth hormone is effective (or will possibly be effective during a trial of therapy)
  - c. based on bone-age x-ray, the predicted height is < the third percentile\*\*Children with familial (genetic) short stature or constitutional delayed growth and development are excluded from review in this section (see exclusions)\*\*
- 3) A 12-month trial of growth hormone is to establish that the child's condition responds to growth hormone

therapy. Authorization for continued therapy should be based on an adequate clinical response defined as either:

- a. growth rate that doubles in the first year of therapy OR
- b. growth increases by  $\geq 3$  cm/year (i.e. in addition to their baseline growth)

### **Adult Growth Hormone Deficiency:**

- a) The patient must be evaluated by an endocrinologist
- b) The patient must have a documented diagnosis of somatropin (growth hormone) deficiency syndrome that is one of the following:
  - 1) Adult onset: growth hormone deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma
  - 2) Childhood onset
- c) The patient must have a negative response to one standard growth hormone stimulation test (maximum peak of  $\leq 5$  ng/ml) measured by radioimmunoassay (polyclonal antibody) or  $< 2.5$  ng/ml measured by immunoradiometric assay (monoclonal antibody). Stimulation tests include insulin tolerance, arginine, growth hormone releasing hormone (GHRH), the combination of arginine and GHRH, the combination of GHRH and growth hormone releasing peptide, and glucagon. The diagnostic test of choice is insulin tolerance; however, it is contraindicated in patients with ischemic heart disease or seizure disorders

### **OR**

- 1) The patient has 2 or more of the following pituitary hormone deficiencies: thyroid stimulating hormone (TSH) deficiency, adrenocorticotropin hormone (ACTH) deficiency, Gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), and arginine vasopressin (AVP) deficiency (central diabetes insipidus) AND
- 2) Serum IGF-I  $< 84\mu\text{g/liter}$  ( $11\text{nmol/liter}$ ) using the Esoterix Endocrinology competitive binding RIA. Other causes of low serum IGF-I must be excluded (e.g. malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy) before using IGF-I as a marker of growth hormone deficiency. Serum IGF-I alone is not specific enough for diagnosis

### **Patients who have undergone brain radiation**

Somatropin or somatrem is recommended for patients who have undergone brain radiation that has affected the normal functioning of the pituitary gland (see Adult Growth Hormone Deficiency #b1 above). Children who have undergone brain radiation and have demonstrated growth hormone deficiency often begin treatment with somatropin when the rate of growth slows significantly.

### **Turner's syndrome**

Somatropin is recommended for girls with short stature associated with Turner's syndrome, demonstrated by chromosome analysis. Patients must be evaluated by a pediatric endocrinologist. Evaluation of growth hormone secretion is not necessary.

### **Short Stature in children with Noonan Syndrome**

Somatropin is indicated for short stature in children with Noonan syndrome. Patients must be evaluated by a pediatric endocrinologist. Evaluation of growth hormone secretion is not necessary.

### **Children with chronic renal insufficiency**

Somatropin is recommended for growth failure in children with chronic renal insufficiency up to the time of kidney transplantation. Patients must be evaluated by a pediatric endocrinologist or a nephrologist. Evaluation of growth hormone secretion is not necessary. Somatropin is also recommended in children who develop chronic renal insufficiency after a kidney transplant.

### **Congenital hypopituitarism**

Either somatropin or somatrem is recommended for infants or children with congenital hypopituitarism. Patients must be evaluated by a pediatric endocrinologist and meet the above criteria for children.

### **Prader-Willi syndrome**

Somatropin is recommended for children with growth failure due to Prader-Willi syndrome. Patients must be evaluated by a pediatric endocrinologist. Evaluation of growth hormone secretion is not necessary. Some patients with Prader-Willi syndrome may meet the criteria for growth hormone deficiency, and most have a diminished serum growth hormone response to stimulation testing.

### **Short children born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including Silver-Russell syndrome**

Somatropin is recommended and patients must meet the following criteria: (Evaluation of growth hormone secretion and bone age is not necessary, although some patients may have a diminished serum growth hormone response to stimulation testing and meet the criteria for children with growth hormone deficiency).

- a) Patient must be evaluated by a pediatric endocrinologist
- b) Patient must be born SGA, defined as birth weight and/or birth length that is  $>2SD$  below the mean for gestational age and gender, and did not have significant catch-up growth by age 2
- c) Age:
  - Patient must be  $\geq 2$  years of age and  $\leq 8$  years
  - If the child is  $> 8$  years of age and prepubertal, coverage is recommended on a one-year trial basis. If growth increases by  $\geq 3$  cm/year (in addition to their baseline growth) with therapy, then authorization for continued therapy is recommended
  - If the child is  $> 8$  years of age and pubertal, growth hormone therapy is not recommended. Efficacy has not been established in pubertal adolescents born SGA
- d) *Height*: The patient's baseline height must be  $<$  the third percentile (i.e.  $>2$  SD below the mean for gender and age, a measure of the degree of short stature)

### **AIDS Wasting Syndrome**

- a) The patient must be HIV-positive and have AIDS-wasting syndrome
- b) The patient must have one of the following: documented, unintentional weight loss of  $\geq 10\%$  from baseline; weight  $<90\%$  of the lower limit of ideal body weight; or body mass index (BMI)  $\leq 20$  Kg/m<sup>2</sup>
- c) The patient must be able to consume or be fed, through parenteral or enteral feedings,  $\geq 75\%$  of energy requirements based on current body weight
- d) The patient must have been on antiretroviral therapy for  $\geq 30$  days prior to beginning GH therapy and will continue antiretroviral therapy throughout the course of GH therapy
- e) Therapy with growth hormone should be limited to 12 weeks in these patients, where possible. (Controlled studies are not available using growth hormone for  $> 12$  weeks in AIDS wasting)

Repeat courses: Repeat 12-week courses of growth hormone may be authorized in patients who have received a previous 12-week course of growth hormone for AIDS wasting provided that they have been off growth hormone for at least 1 month and meet all above criteria.

### **HIV-associated failure to thrive**

Children aged  $<17$  years with HIV-associated failure to thrive must meet the following criteria:

- a) The patient must be able to consume or be fed, through parenteral or enteral feedings,  $\geq 75\%$  of maintenance energy requirements based on current body weight



- b) The patient must have been on antiretroviral therapy for  $\geq 30$  days prior to beginning somatropin therapy and will continue antiretroviral therapy throughout the course of somatropin treatment
- c) The patient should be reevaluated after 12 weeks to assess the risks vs. benefits of somatropin therapy. Children with HIV-associated failure to thrive may require several months of growth hormone therapy

### **Short-Stature Homeobox-containing Gene Deficiency (SHOX-D)**

Somatropin is recommended for children with short stature associated with Short-Stature Homeobox-containing Gene Deficiency, demonstrated by chromosome analysis. Patients must be evaluated by a pediatric endocrinologist. Evaluation of growth hormone secretion is not necessary.

### **Traumatic Brain Injury and Aneurysmal Subarachnoid Hemorrhage**

In patients with these conditions, growth hormone deficiency may be transient. As such, growth hormone stimulation testing is recommended at least 12 months after the event before determining if treatment is appropriate.

### **Exclusions:**

- I. Coverage of Serostim<sup>®</sup> is not recommended in the following circumstances: HIV-infected patients with alterations in body fat distribution (e.g., increased abdominal girth, buffalo hump). Controlled studies are not available
- II. Coverage of growth hormone is not recommended in the following circumstances unless above criteria have been met:
  - a) Constitutional delayed growth and development
  - b) Idiopathic Short Stature
  - c) Familial short stature (normal short stature, non-growth hormone deficient short stature). These children usually have a normal growth velocity, and a bone-age x-ray indicates their predicted height is appropriate for their mid-parenteral heights
  - d) Down's syndrome
  - e) Corticosteroid-induced short stature, including chronic glucocorticoid-dependent conditions (e.g., asthma, IBD, juvenile RA, & post renal, heart, liver, and bone marrow transplantation)
  - f) Kidney transplant patients with a functional renal allograft. Note: If chronic renal insufficiency develops after transplantation, the patient will meet the criteria for chronic renal insufficiency
  - g) Congenital adrenal hyperplasia (CAH). There is limited evidence suggesting that GH alone or in combination with LHRH analog improves final adult height in patients with CAH. Use of GH for congenital adrenal hyperplasia will be considered on a case-by-case basis.
  - h) Liver transplantation
  - i) Bone marrow transplantation without total body irradiation (cranial radiation)

- j) Bony dysplasias (achondroplasia, hypochondroplasia). Short-term treatment with GH increases growth velocity in some patients, but there are no prospective studies assessing linear growth until achievement of final adult height. Use of GH in bony dysplasias will be considered on a case-by-case basis.
- k) Growth hormone neurosecretory dysfunction
- l) Hypophosphatemic rickets
- m) Myelomeningocele
- n) Dilated cardiomyopathy and heart failure
- o) Adult short stature
- p) Athletic ability (enhancement)
- q) Aging - Clinical evidence does not support the use of growth hormone as an anti-aging therapy
- r) Infertility
- s) Metabolic conditions, as an adjunct to nutritional therapy in critically ill catabolic patients receiving specialized nutritional support to promote protein anabolism
- t) Adult obesity
- u) Osteoporosis, postmenopausal or idiopathic in men
- v) Short-bowel syndrome (for use with glutamine)
- w) Elderly patients with end-stage renal disease undergoing hemodialysis. More & larger studies are required to assess the effects of growth hormone on quality of life, morbidity, and mortality
- x) HIV-infected patients with alterations in body fat distribution (e.g., increased abdominal girth, buffalo hump)
- y) Crohn's disease
- z) Chronic fatigue syndrome. Evidence from clinical trials is insufficient to conclude whether growth hormone therapy is effective
- aa) Fibromyalgia
- bb) Cystic fibrosis. Short-term treatment with growth hormone increases height, weight, lean mass, bone mineral content, and decreases hospitalization in some patients, with effect sustained up to 1 year post-treatment. However there are no prospective studies assessing linear growth until achievement of final adult height. Use of growth hormone in cystic fibrosis should be considered on a case-by-case basis.
- cc) Cerebral palsy. Evidence from clinical trials is insufficient to conclude whether growth hormone therapy is effective
- dd) Prader-Willi Syndrome: severe obesity, uncontrolled diabetes, untreated severe obstructive sleep apnea, active cancer and active psychosis. This includes pediatric patients.

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Last Reviewed: 6/27/16



**Ilaris® (canakinumab)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Diagnosis:**

- The treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including:
  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
- Systemic Juvenile Idiopathic Arthritis in children 2 years of age and older

**Approval Criteria:**

- Diagnosis of Cryopyrin Associated Periodic Syndromes (CAPS) including:
  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)

**AND**
- The member is 4 years of age and older

**AND**
- The request is being prescribed by a specialist or in consultation with a specialist (e.g., an immunologist, allergist, dermatologist, rheumatologist, neurologist, etc.)

**OR**
- Diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA)

**AND**
- The member is 2 years of age and older

**AND**
- The member has had an inadequate response, contraindication, adverse reaction, or allergy to anakinra (Kineret®)  
(Note: refer to appendices 1 & 2 for recommended initial and continued therapies).

All other indications will be evaluated on a case-by case basis.

**Initial authorizations:** Initial approvals shall be granted for up to 6 months

**Recertification:**

- Improvement per physician assessment of overall disease activity
- Reauthorization requests for CAPS or SJIA shall be granted for up to 12 months



## **Hepatitis C Medications Prior Authorization Criteria**

**Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir), Daklinza® (daclatasvir), Zepatier™ (elbasvir/grazoprevir), Olysio® (simeprevir), Viekira Pak® (ombitasvir/paritaprevir/ritonavir; dasabuvir), Technivie® (ombitasvir/paritaprevir/ritonavir), pegylated interferon (Pegasys® & Peg-Intron®), and ribavirin**

### **For MassHealth members:**

**Harvoni™ is the preferred combination agent HCV medication**

**Sovaldi™ and Daklinza™ are the preferred single-agent HCV medications**

**Epclusa will be considered for Genotypes 2 and 3**

**Current prior authorizations will be grandfathered for the life of the prior authorization**

### **For Commercial and Connector members:**

**Harvoni™ and Epclusa® are the preferred combination agent HCV medication**

**Current prior authorizations will be grandfathered for the life of the prior authorization**

**NHP will continue to review non-preferred products on a case by case basis and cover when medically necessary.**

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**All Hepatitis C medications are specialty products; dispensing is available only when obtained from any NHP contracted specialty pharmacy including CVS Caremark Specialty Pharmacy.**

### **How do I obtain a prior authorization for a hepatitis C medication or medication regimen?**

- Download a CVS fax form & send to 1-866-249-6155 ([hyperlink to PA fax form](#)).
- Contact CVS Caremark Specialty Pharmacy at 1-866-814-5506 or NHP at (855) 444-4NHP (4647) for questions.

### **Approvable Diagnosis**

- Chronic hepatitis C (CHC) infection

### **Approval Criteria**

- Patient is new to NHP and has already been started and stabilized on a regimen of hepatitis C medication(s) as part of an appropriate treatment regimen (e.g. genotype, combination therapy, dose, treatment duration, etc.) for chronic hepatitis C infection
- **OR**
- Patient has a diagnosis of chronic hepatitis C (CHC) infection **AND**
- Patient has a detectable HCV RNA viral load drawn from within the last 6 months **AND**
- Patient has documented liver disease **AND**
- Patient has documentation of stage of hepatic fibrosis through one of the following:
  - a) Liver biopsy confirming a Metavir stage
  - b) Transient elastography (FibroScan®) score
  - c) Fibrotest (such as FibroSure™) score
  - d) AST to Platelet Ratio Index (APRI) score
  - e) Severe extra hepatic manifestations/symptoms

### **AND all of the following:**

- Patient has demonstrated understanding of the proposed treatment plan and has displayed the ability to adhere to medications and clinical appointments **AND**
- The requested dose and duration of therapy are consistent with published label indications for each medication and the

AASLD published treatment guidelines, management in Tables 1 through 3.

- Provider will submit HCV RNA viral load 12 weeks (SVR12) after completion of therapy to assess virologic cure.
- For therapies exceeding 12 weeks, provider will submit HCV RNA viral load at week 4 of treatment. Repeat HCV RNA should be drawn at 6 week if viral load is detectable at week 4.
- All other requests will be reviewed on a case-by-case basis consistent with approved FDA labeling and/or recognized treatment guidelines.

**Table 1: Hepatitis C Regimens for Treatment-Naïve Patients and Treatment Experienced Patients by Genotype**

Genotype	Treatment History		Regimen		Duration		
Genotype 1a	Treatment Naïve		Without cirrhosis	Daily Zepatier (without baseline NS5A polymorphisms) <b>Class I, Level A</b>	12 weeks		
				Daily Harvoni <b>Class I, Level A</b> HCV RNA <6,000,000 IU/mL (8 weeks)* HCV RNA >6,000,000 IU/mL (12 weeks)	8-12 weeks*		
				Daily Epclusa <b>Class I, Level A</b>	12 weeks		
			With compensated cirrhosis	Daily Zepatier (without baseline NS5A polymorphisms) <b>Class I, Level A</b>	12 weeks		
				Daily Harvoni <b>Class I, Level A</b>	12 weeks		
				Daily Epclusa <b>Class I, Level A</b>	12 weeks		
	Treatment Experienced		Without cirrhosis	Daily Zepatier (without baseline NS5A polymorphisms) <b>Class I, Level A</b>	12 weeks		
				Daily Harvoni <b>Class I, Level A</b>	12 weeks		
				Daily Epclusa <b>Class I, Level A</b>	12 weeks		
			With compensated cirrhosis	Daily Zepatier (without baseline NS5A polymorphisms) <b>Class I, Level A</b>	12 weeks		
				Daily Harvoni + weight-based ribavirin <b>Class I, Level A</b>	12 weeks		
				Daily Epclusa <b>Class I, Level A</b>	12 weeks		
			Prior sofosbuvir plus RBV +/- PEG-INF regimen failed	Without cirrhosis	Daily Harvoni + weight-based ribavirin <b>Class IIa, Level B</b>	12 weeks	
				With compensated cirrhosis	Daily Harvoni + weight-based ribavirin <b>Class IIa, Level B</b>	24 weeks	
			Prior NS3 PI (telaprevir, boceprevir, or simeprevir) + PEG-INF/RBV regimen failed	Without cirrhosis	Daily Harvoni <b>Class I, Level A</b>	12 weeks	
					Daily Epclusa <b>Class I, Level A</b>	12 weeks	
				With compensated cirrhosis	Daily Harvoni + weight-based ribavirin <b>Class I, Level A</b>	12 weeks	
					Daily Epclusa <b>Class I, Level A</b>	12 weeks	
			Prior simeprevir + sofosbuvir regimen failed	Without cirrhosis	Consider deferral of treatment as there is limited data for treatment-experienced patients (no prior NS5A treatment) with HCV genotype 1 infection who do not have cirrhosis, and do not have reasons for urgent retreatment. <b>Class IIb, Level C</b>		
				With compensated cirrhosis	Testing for resistance-associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors is recommended for treatment experienced patients with HCV genotype 1 infection who have compensated cirrhosis, or have reasons for urgent retreatment. The specific drugs used in the retreatment regimen should be tailored to the results. Refer to AASLD guidelines. <b>Class II, Level C</b>		

		Prior NS5A inhibitor regimen failed <sup>‡</sup>	Without cirrhosis	Consider deferral of treatment as there is limited data for treatment-experienced patients with HCV genotype 1 infection who do not have cirrhosis, and do not have reasons for urgent retreatment. <b>Class IIb, Level C</b>	
			With compensated cirrhosis	Testing for resistance-associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors is recommended for treatment experienced patients with HCV genotype 1 infection who have compensated cirrhosis, or have reasons for urgent retreatment. The specific drugs used in the retreatment regimen should be tailored to the results. Refer to AASLD guidelines. <b>Class IIb, Level C</b>	
Genotype 1b	Treatment Naïve		Without cirrhosis	Daily Zepatier <b>Class I, Level A</b>	12 weeks
				Daily Harvoni <b>Class I, Level A</b> HCV RNA <6,000,000 IU/mL (8 weeks)* HCV RNA >6,000,000 IU/mL (12 weeks)	8-12 weeks
				Daily Epclusa <b>Class I, Level A</b>	12 weeks
			With compensated cirrhosis	Daily Zepatier <b>Class I, Level A</b>	12 weeks
				Daily Harvoni <b>Class I, Level A</b>	12 weeks
				Daily Epclusa <b>Class I, Level A</b>	12 weeks
	Treatment Experienced	Prior PEG-IFN + RBV failed	Without cirrhosis	Daily Zepatier <b>Class I, Level A</b>	12 weeks
				Daily Harvoni <b>Class I, Level A</b>	12 weeks
				Daily Epclusa <b>Class I, Level A</b>	12 weeks
			With compensated cirrhosis	Daily Zepatier <b>Class I, Level A</b>	12 weeks
				Daily Harvoni + weight based ribavirin <b>Class I, Level A</b>	12 weeks
				Daily Epclusa <b>Class I, Level A</b>	12 weeks
		Prior sofosbuvir plus RBV +/- PEG-INF regimen failed	Without cirrhosis	Daily Harvoni + weight-based ribavirin <b>Class IIa, Level B</b>	12 weeks
			With compensated cirrhosis	Daily Harvoni + weight-based ribavirin <b>Class IIa, Level B</b>	24 weeks
		Prior NS3 PI (telaprevir, boceprevir, or simeprevir) + PEG-INF/RBV regimen failed	Without cirrhosis	Daily Harvoni <b>Class I, Level A</b>	12 weeks
				Daily Epclusa <b>Class I, Level A</b>	12 weeks
			With compensated cirrhosis	Daily Harvoni + weight-based ribavirin <b>Class I, Level A</b>	12 weeks
				Daily Epclusa <b>Class I, Level A</b>	12 weeks
		Prior simeprevir + sofosbuvir regimen failed	Without cirrhosis	Consider deferral of treatment as there is limited data for treatment-experienced patients (no prior NS5A treatment) with HCV genotype 1 infection who do not have cirrhosis, and do not have reasons for urgent retreatment. <b>Class IIb, Level C</b>	
			With compensated cirrhosis	Testing for resistance-associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors is recommended for treatment experienced patients with HCV genotype 1 infection who have compensated cirrhosis, or have reasons for urgent retreatment. The specific drugs used in the retreatment regimen should be tailored to the results. Refer to AASLD guidelines. <b>Class II, Level C</b>	
		Prior NS5A inhibitor regimen failed <sup>‡</sup>	Without cirrhosis	Consider deferral of treatment as there is limited data for treatment-experienced patients with HCV genotype 1 infection who do not have cirrhosis, and do not have reasons for urgent retreatment. <b>Class IIb, Level C</b>	
			With compensated cirrhosis	Testing for resistance-associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors is recommended for treatment experienced patients with HCV genotype 1 infection who have compensated cirrhosis, or have reasons for urgent retreatment. The specific drugs used in the retreatment regimen should be tailored to the results. Refer to AASLD guidelines. <b>Class IIb, Level C</b>	



\*Shortening treatment of Harvoni to 8 weeks is not recommended for HIV co-infected patients, African-American patients, or those with known IL28B polymorphism CT or TT.

≠ NS5A inhibitors single agents: 1) Daklinza, 2) ombitasvir in Viekira-Pak, 3) ledipasvir in Harvoni, and 4) elbasvir in Zepatier.

△The concomitant use of Daklinza (daclatasvir) with cytochrome P450 3A/4 inducers and inhibitors may require a dose adjustment.

<b>Genotype 2</b>	<b>Treatment naïve</b>		<b>Without cirrhosis</b>	Daily Epclusa <b>Class I, Level A</b>	12 weeks
			<b>With compensated cirrhosis</b>	Daily Epclusa <b>Class I, Level A</b>	12 weeks
	<b>Treatment Experienced</b>	<b>Prior PEG-IFN + RBV failed</b>	<b>Without cirrhosis</b>	Daily Epclusa <b>Class I, Level A</b>	12 weeks
			<b>With compensated cirrhosis</b>	Daily Epclusa <b>Class I, Level A</b>	12 weeks
		<b>Prior sofosbuvir + RBV failed</b>	<b>+/- compensated cirrhosis</b>	Daily Epclusa + weight based ribavirin <b>Class IIa, Level C</b>	12 weeks
<b>Genotype 3</b>	<b>Treatment naïve</b>		<b>Without cirrhosis</b>	Daily Sovaldi + Daklinza <b>Class I, Level A<sup>Δ</sup></b>	12 weeks
				Daily Epclusa <b>Class I, Level A</b>	12 weeks
			<b>With compensated cirrhosis</b>	Daily Epclusa <b>Class I, Level A<sup>†</sup></b>	12 weeks
	<b>Treatment Experienced</b>	<b>Prior PEG-IFN + RBV failed</b>	<b>Without cirrhosis<sup>†</sup></b>	Daily Sovaldi + Daklinza <b>Class I, Level A<sup>Δ†</sup></b>	12 weeks
				Daily Epclusa <b>Class I, Level A<sup>†</sup></b>	12 weeks
		<b>Prior sofosbuvir + RBV failed</b>	<b>With compensated cirrhosis</b>	Daily Epclusa + weight based ribavirin <b>Class I, Level B</b>	12 weeks
			<b>+/- compensated cirrhosis</b>	Daily Epclusa + weight based ribavirin <b>Class IIa, Level C</b>	12 weeks

<sup>Δ</sup>The concomitant use of Daklinza (daclatasvir) with cytochrome P450 3A/4 inducers and inhibitors may require a dose adjustment.

<sup>†</sup>RAV testing for Y93H is recommended and ribavirin should be included if present.

Genotype 4	Treatment naïve		+/- compensated cirrhosis	Daily Epclusa <b>Class I, Level A</b>	12 weeks
				Daily Zepatier <b>Class IIa, Level B</b>	12 weeks
				Daily Harvoni <b>Class IIa, Level B</b>	12 weeks
	Treatment Experienced	Prior PEG-IFN + RBV failed	Without cirrhosis	Daily Epclusa <b>Class I, Level A</b>	12 weeks
				Daily Harvoni <b>Class IIa, Level B</b>	12 weeks
			With compensated cirrhosis	Daily Epclusa <b>Class I, Level A</b>	12 weeks
Daily Harvoni + weight based ribavirin (if ribavirin eligible) <b>Class IIa, Level B</b>				12 weeks	
Genotype 5	Treatment Naïve		+/- compensated cirrhosis	Daily Epclusa <b>Class I, Level A</b>	12 weeks
				Daily Harvoni <b>Class IIa, Level B</b>	12 weeks
	Treatment Experienced		Prior PEG-IFN + RBV failed	Daily Epclusa <b>Class IIa, Level B</b>	12 weeks
				Daily Harvoni <b>Class IIa, Level C</b>	12 weeks
Genotype 6	Treatment naïve		+/- compensated cirrhosis	Daily Epclusa <b>Class I, Level A</b>	12 weeks
				Daily Harvoni <b>Class IIa, Level B</b>	12 weeks
	Treatment Experienced		Prior PEG-IFN + RBV failed	Daily Epclusa <b>Class IIa, Level B</b>	12 weeks
				Daily Harvoni <b>Class IIa, Level C</b>	12 weeks

**Table 2: Hepatitis C Regimens for HIV/HCV Co-Infected Patients**

Antiretroviral drug switches, when needed, should be done in collaboration with the HIV practitioner. For HIV antiretroviral and HCV direct-acting antiviral combinations not addressed below, expert consultation is recommended. <b>Class I, Level A</b>
Daklinza requires dose adjustment with ritonavir-boosted atazanavir (a decrease to 30mg daily) and efavirenz or etravirine (an increase to 90mg daily). <b>Class IIa, Level B</b>
Zepatier should be used with antiretroviral drugs which it does not have clinically significant interactions: abacavir, emtricitabine, enfuvirtide, lamivudine, raltegravir, dolutegravir, rilpivirine, and tenofovir. <b>Class IIa, Level B</b>
Olysio should be used with antiretroviral drugs with which it does not have clinically significant interactions: abacavir, emtricitabine, enfuvirtide, lamivudine, maraviroc, raltegravir, (and probably dolutegravir), rilpivirine, and tenofovir. <b>Class IIa, Level B</b>
Velpatasvir increases tenofovir levels; therefore, concomitant use with Epclusa mandates consideration of renal function and should be avoided in those with CrCl below 60 mL/min. In patients with CrCl > 60 mL/min concomitant dosing of velpatasvir and TDF with ritonavir-boosted or cobicistat-boosted regimens did not result in renal toxicity in 56 subjects. Renal monitoring is recommended during the dosing period. Tenofovir alafenamide (TAF) may be an alternative to TDF during sofosbuvir/velpatasvir treatment for patients who take cobicistat or ritonavir as part of their antiretroviral therapy. <b>Class IIa, Level B</b>
Fixed-dose combination of Harvoni increases tenofovir levels; therefore, concomitant use mandates consideration of creatinine clearance (CrCl) rate and should be avoided in those with CrCl <60 mL/min. Because potentiation of this effect is expected when tenofovir is used with ritonavir-boosted or cobicistat-boosted regimens, ledipasvir should be avoided with this combination (pending further data) unless antiretroviral regimen cannot be changed and the urgency of treatment is high. For combinations expected to increase tenofovir levels, baseline and ongoing assessment for tenofovir nephrotoxicity is recommended. Tenofovir alafenamide (TAF) may be an alternative to TDF during ledipasvir/sofosbuvir treatment for patients who take cobicistat or ritonavir as part of their antiretroviral therapy. <b>Class IIa, Level C</b>
For combinations expected to increase tenofovir levels, baseline and ongoing assessment for tenofovir nephrotoxicity is recommended. <b>Class IIa, Level C</b>
Viekira Pak should be used with antiretroviral drugs with which they do not have substantial interactions: atazanavir, dolutegravir, emtricitabine, enfuvirtide, lamivudine, raltegravir, and tenofovir. The dose of ritonavir used for boosting of HIV protease inhibitors may need to be adjusted (or held) when administered with Viekira Pak and then restored when HCV treatment is completed. The HIV protease inhibitor should be administered at the same time as the fixed-dose HCV combination. <b>Class IIa, Level C</b>

**Table 3: Hepatitis C Regimens for Patients with Renal Impairment**

No dosage adjustment is required for patients with mild to moderate renal impairment (CrCl 30 mL/min-80 mL/min) when using daclatasvir (60mg*), Harvoni, Epclusa, or fixed-dose combination of paritaprevir (150 mg)/ritonavir (100 mg)/ombitasvir (25 mg) with (or without for HCV genotype 4 infection) twice-daily dosed dasabuvir (250 mg), Olysio, or Sovaldi to treat or retreat HCV infection in patients with appropriate genotypes. <b>Class I, Level A</b>
For patients with genotype 1a, or 1b, or 4 infection and CrCl below 30 mL/min, for whom treatment has been elected before kidney transplantation, daily Zepatier for 12 weeks is a Recommended regimen. <b>Class IIa, Level B</b>
For patients with genotype 1b infection and CrCl below 30 mL/min for whom the urgency to treat is high and treatment has been elected before kidney transplantation, daily Viekira Pak for 12 weeks is a Recommended regimen. <b>Class IIb, Level B</b>
For patients with HCV genotype 2, 3, 5, or 6 infection and CrCl below 30 mL/min for whom the urgency to treat is high and treatment has been elected before kidney transplantation, PEG-IFN and dose-adjusted ribavirin** (200 mg daily) is a Recommended regimen. <b>Class IIb, Level B</b>
For HCV genotype 1a infection and CrCl below 30 mL/min, daily fixed-dose combination of Viekira Pak and dose-adjusted ribavirin** (200 mg daily) for 12 weeks is an Alternative regimen. <b>Class IIb, Level B</b>

### **\*\*Notes\*\***

- **Non-responders (or null responders)** are defined as those who experienced less than a 2 log decline in viral load during a previous 12 week treatment course (viral load was never undetectable). Partial responders experienced greater viral load suppression than non-responders, but viral load was never undetectable during treatment. These individuals have lower re-treatment success.
- **Relapsers** are defined as those who achieved undetectable HCV RNA blood levels during previous treatment who relapsed after treatment cessation. Relapsers should be treated as if they are naïve to therapy. These individuals tend to do well with re-treatment.
- For patients who are currently taking an antacid, H2 antagonist, or proton pump inhibitor and require a Epclusa- or Harvoni-containing regimen, NHP requires documentation of how this drug interaction will be managed.

### **References**

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**Humira® (adalimumab)  
Prior Authorization criteria  
Drug Protocol Management**

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**Humira® (adalimumab) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Humira®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Rheumatoid arthritis (RA)
- Juvenile idiopathic arthritis (JIA)
- Psoriatic arthritis
- Ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis
- Crohn's disease
- Ulcerative colitis

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Humira® for an approvable indication  
**OR**
- Patient has a diagnosis of rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis  
**AND**
- Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD\*, if methotrexate is contraindicated) \*†  
**OR**
- Patient is  $\geq 2$  years of age **AND**
- Patient has a diagnosis of juvenile idiopathic arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with the recommended initial and continued therapies (please refer to Appendices 1 & 2 below)  
**OR**
- Patient has a diagnosis of Crohn's disease or ulcerative colitis **AND**
- Patient has experienced an inadequate response or intolerance to one or more conventional immunomodulator therapies‡  
**OR**
- Patient has a diagnosis of moderate to severe chronic plaque psoriasis affecting  $\geq 10\%$  body surface area **AND**
- Patient has experienced an inadequate response or intolerance to at least **one (1)** agent from at least **two (2)** of the following **three (3)** categories:
  - **Topical agents:** emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene
  - **Systemic agents:** methotrexate, sulfasalazine, cyclosporine, tacrolimus, acitretin, mycophenolate mofetil, azathioprine, hydroxyurea, etc.

- **Phototherapy:** ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB), etc.
- \* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline
- \*† Methotrexate/DMARD trial requirement may be overridden for patients with documented axial disease in ankylosing spondylitis or psoriatic arthritis whose condition is not adequately controlled with NSAIDs AND for RA patients with documented high disease activity (advanced disease) with features of a poor prognosis (i.e., functional limitations, extra-articular disease, positive rheumatoid factor, or anti-cyclic citrullinated peptide antibodies, & bony erosions by radiograph)
- ‡ Conventional immunomodulator therapies include methotrexate, cyclosporine, azathioprine, tacrolimus, and 6-mercaptopurine

Initial approvals may be issued for up to 6 months for all indications except plaque psoriasis; initial approvals for plaque psoriasis may be issued for up to 3 months.

### Reauthorization Criteria

- Improvement per physician assessment of overall disease activity

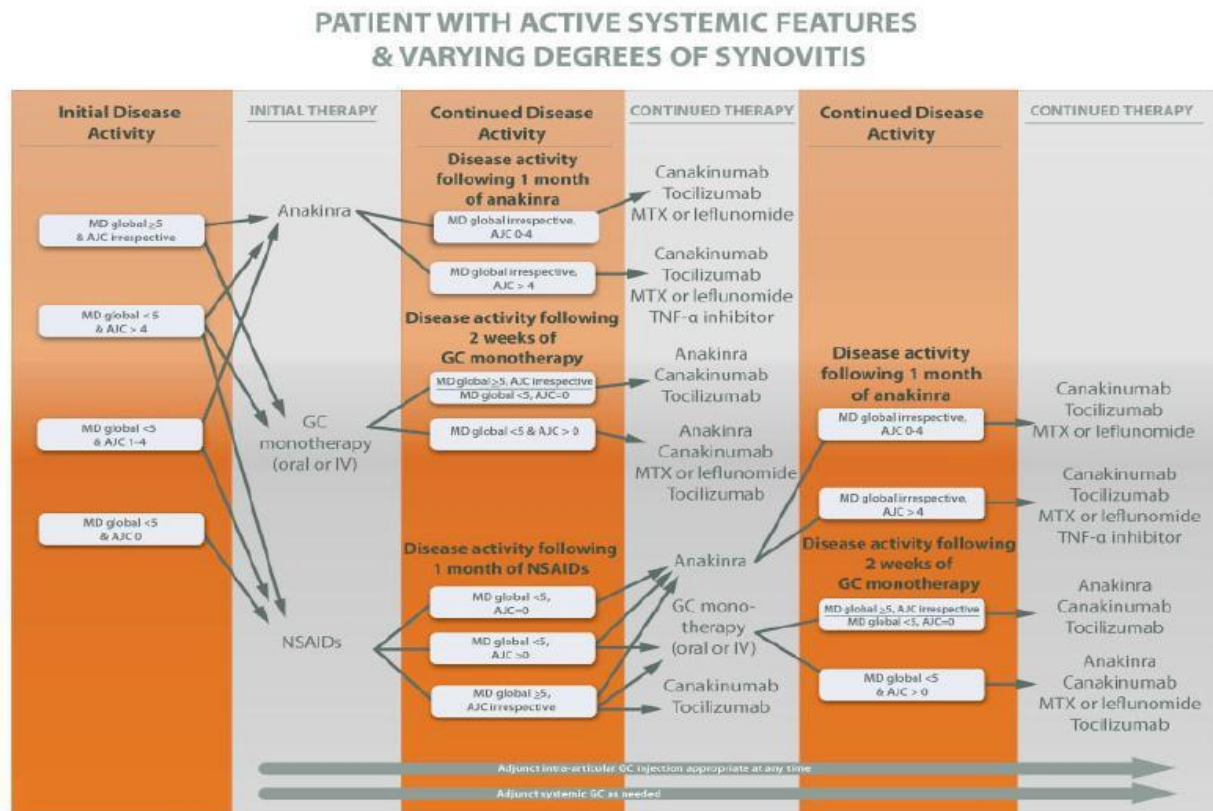
Reauthorizations may be granted for up to 1 year for all indications except plaque psoriasis, Crohn's disease, & ulcerative colitis; reauthorizations for plaque psoriasis, Crohn's disease, & ulcerative colitis may be issued for up to 6 months.

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- Last updated/reviewed: 4/6/15

## Appendix 1



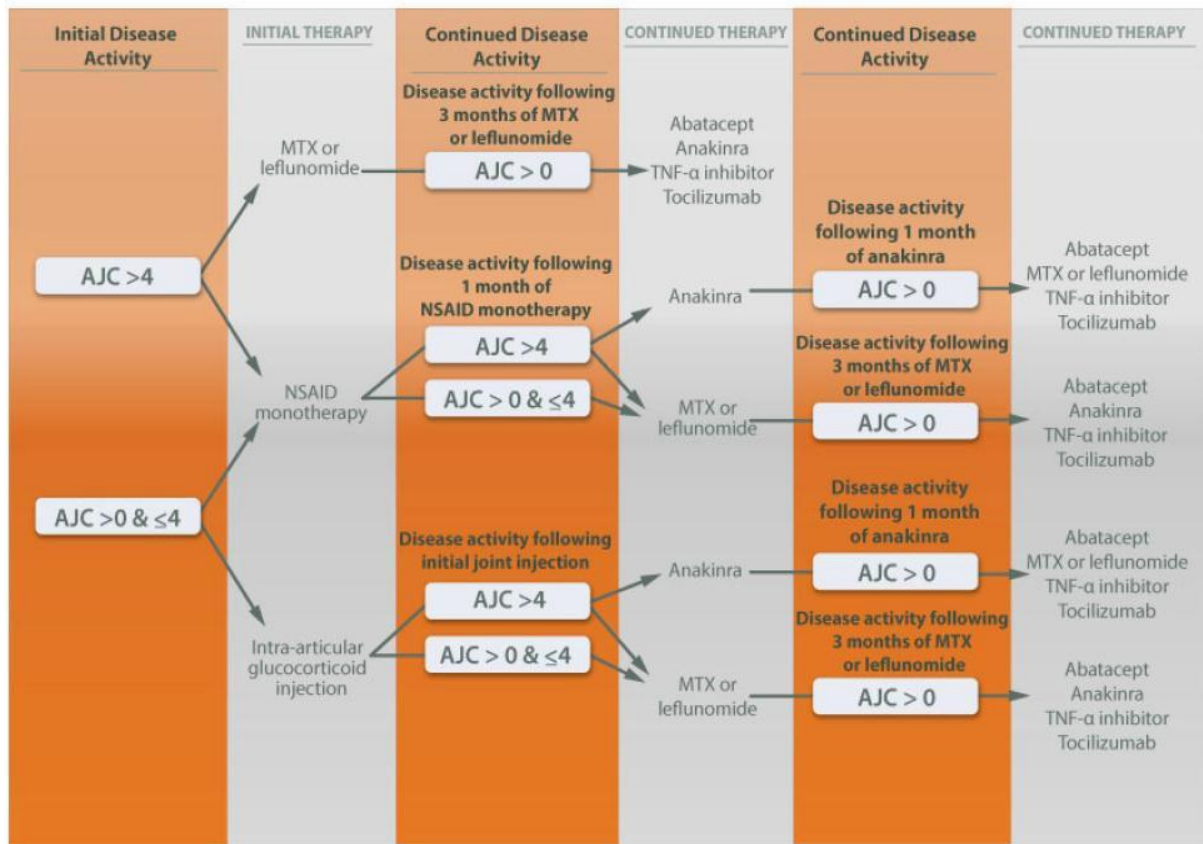
**Figure 1.** Treatment pathways for patients with active systemic features and varying degrees of synovitis. The Task Force Panel was asked to consider the treatments among patients with active systemic features and a physician global assessment (MD global) of  $< 5$  or  $\geq 5$  on a 10-point numerical rating scale (0–10 visual analog scale, where 0 = no disease activity and 10 = the most severe) and by active joint count (AJC; 0 joints, 1–4 joints, or  $> 4$  joints). If a recommendation is noted to be irrespective of the AJC or MD global, the recommendation was for children with an AJC  $\geq 0$  or an MD global  $> 0$ , respectively. Adjunct systemic glucocorticoids (GCs) and/or intraarticular GCs may be added at any point. Children may qualify for  $> 1$  pathway, in which case it is left to the provider's discretion to choose the path they feel is most appropriate based upon specific patient characteristics and/or patient and family preferences. Steps in the progression of therapy can be additive or sequential, except that therapies with a biologic agent are sequential (combination therapy with a biologic agent is not endorsed). The recommendations in this figure are for patients with active systemic features. If the systemic features (but not the arthritis) respond to therapy, then subsequent treatment decisions should be based upon the recommendations in Figure 2. NSAIDs = nonsteroidal antiinflammatory drugs; IV = intravenous; MTX = methotrexate; TNF $\alpha$  = tumor necrosis factor  $\alpha$ .

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512



## Appendix 2

### PATIENT WITHOUT ACTIVE SYSTEMIC FEATURES & VARYING DEGREES OF SYNOVITIS



**Figure 2.** Treatment pathways for patients without active systemic features and with varying degrees of synovitis. The Task Force Panel was asked to rate the appropriateness of therapies based on the total number of active joints ( $\leq 4$  or  $> 4$ ). Children may qualify for  $> 1$  pathway, in which case it is left to the provider's discretion to choose the path they feel is most appropriate based upon specific patient characteristics and/or patient and family preferences. Steps in the progression of therapy can be additive or sequential, except that therapies with a biologic agent are sequential (combination therapy with a biologic agent is not endorsed). AJC = active joint count; MTX = methotrexate; NSAID = nonsteroidal antiinflammatory drug; IV = intravenous; TNF $\alpha$  = tumor necrosis factor  $\alpha$ .

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512



**Increlex® (mecasermin)  
Prior Authorization  
Drug Protocol Management**

Increlex® (mecasermin) Criteria:

Approval of Increlex will be granted if the patient meets the following criteria:

- d) Member has growth hormone gene deletion AND neutralizing antibodies to growth hormone, OR primary insulin-like growth factor (IGF)-1 deficiency (IGFD), defined by the following:
  - i. Height standard deviation score  $\leq -3.0$   
**AND**
  - ii. Basal IGF-1 standard deviation score  $\leq -3.0$   
**AND**
  - iii. Normal or elevated growth hormone level  
**AND**
- e) Member is  $\geq 2$  years old (safety and efficacy has not been established in patients  $< 2$  years)  
**AND**
- f) Member has documentation of open epiphyses  
**AND**
- g) Member is under the care of an endocrinologist or a specialist trained to diagnose & treat growth disorders

Contraindications to therapy:

The use of Increlex® is contraindicated in the following:

- a) Active or suspect neoplasm (cancer)
- b) Closed epiphyses
- c) Intravenous administration

Exclusions:

- a) Primary IGFD with a height standard deviation (SD) of  $> -3.0$  and/or an IGF-1 SD score of  $> -3.0$ .
  - i) Primary IGFD may have mutations in the GH receptor (GHR), post-GHR signaling pathway including the IGF-1 gene, as these patients are GH deficient and are unlikely to respond to exogenous GH treatment
- b) Idiopathic short stature
- c) Secondary IGF-1 deficiency which includes:
  - i) Growth hormone deficiency
  - ii) Malnutrition
  - iii) Hypothyroidism
  - iv) Chronic treatment with anti-inflammatory steroids

**Notes:** Severe Primary IGFD includes classical and other forms of growth hormone insensitivity. Patients with

Primary IGFD may have mutations in the GH receptor (GHR), post-GHR signaling pathway including the IGF-1 gene. They are not GH deficient, and therefore, they cannot be expected to respond adequately to exogenous GH treatment.

Increlex® is not intended for use in subjects with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. Thyroid and nutritional deficiencies should be corrected before initiating Increlex® treatment.

Approved: June 18, 2007 NHP P&T Committee

Reviewed & Updated: 06/16/08 P&T Mtg

Reviewed: 06/15/09; 06/21/2010; 06/27/11; 06/25/12; 06/24/13; 06/23/14, 6/27/16 P&T Mtg



**PCSK9 Inhibitors  
Drug Protocol Management  
Prior Authorization Criteria**

**Criteria for Hyperlipidemia requests:**

Requests for a PCSK9 Inhibitor must meet all of the following:

1. Documentation of the diagnosis of hyperlipidemia
2. Low-fat diet and exercise
3. Prescribed by or in consultation with a cardiologist or lipid specialist
4. High risk patient defined as < 75 years of age with clinical ASCVD, baseline LDL-C  $\geq 190$ mg/dl or 40-75 years of ages with diabetes and ASCVD risk  $\geq 7.5\%$
5. Plus one of the scenarios below:

**Criteria for Homozygous Familial Hypercholesterolemia (HoFH) requests:**

Requests for a PCSK9 Inhibitor must meet all of the following:

1. Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9 or autosomal recessive hypercholesterolemia (ARH) adaptor gene locus **OR**
2. Untreated/pretreatment LDL > 500mg/dL with at least one of the following:
  - a. Cutaneous or tendonous xanthoma before 10 years of age
  - b. History of early vascular disease (men < 55 years of age, women < 60 years of age or both sides of the family if parental LDL-C unknown)
  - c. Elevated LDL-C levels before lipid-lowering therapy consistent with heterozygous FH in both parents where LDL levels are known (>250mg/dL in a patient aged 30 or more, > 220mg/dL for patients aged 20 to 29, >190 mg /dL in patients under age 20)
3. Low-fat diet and exercise
4. Prescribed by or in consultation with a cardiologist or lipid specialist
5. Plus one of the scenarios below:

**Criteria for Heterozygous Familial Hypercholesterolemia (HeFH) requests:**

Requests for a PCSK9 Inhibitor must meet all of the following:

1. Genetic confirmation of a mutation in the LDL receptor, ApoB, PCSK9 **OR**
2. Untreated/pretreatment LDL >190mg/dL in adults or >155mg/dL in child less than 16 years old with the presence cutaneous or tendonous xanthoma in patient, first degree relative or second degree relative
3. Low-fat diet and exercise
4. Prescribed by or in consultation with a cardiologist or lipid specialist
5. Plus one of the scenarios below:

## **Scenarios:**

### **A. High-Intensity Statin**

#### **All of the following**

1. Patient has had at least 3 months of therapy with:
  - a. atorvastatin 40 -80 mg OR
  - b. rosuvastatin  $\geq 20$ mg
2. Add-on therapy with Zetia (ezetimibe) or bile sequestrants to maximum tolerated dose of statin
3. Results in an LDL-C reduction of  $<50\%$  from baseline
4. Statin therapy will be continued with PCSK9 therapy

### **B. Moderate- Intensity Statin**

#### **All of the following:**

1. Patient has an intolerance or contraindications to high-intensity statin therapy
2. Patient has had at least 3 months of therapy with:
  - a. atorvastatin 10-20 mg
  - b. rosuvastatin 5-10 mg
  - c. simvastatin  $\geq 20$ mg
  - d. pravastatin  $\geq 40$ mg
  - e. lovastatin 40mg
  - f. fluvastatin XL 80mg
  - g. fluvastatin 40mg BID
  - h. pitavastatin  $\geq 2$ mg
3. Add-on therapy with Zetia (ezetimibe) or bile sequestrants to maximum tolerated dose of statin
4. Results in an LDL-C reduction of  $<50\%$  from baseline
5. Statin therapy will be continued with PCSK9 therapy

### **C. Intolerance to Statins**

Patient experienced one of the following symptoms to at least two different statins (one of the statins must include pravastatin 40mg or rosuvastatin 5mg)

- a. Myalgia (muscle symptoms without CK elevations)
- b. Myositis (muscle symptoms with CK elevations  $<10$  times ULN)

### **D. Contraindications to Statins**

1. Patient has a labeled contraindication to all statins as documents in medical records **OR**
2. Patient has experienced
  - a. Rhabdomyolysis or muscle symptoms with CK elevations  $\geq$  times ULN

## **Initial Approvals for 6 months**

### **Reauthorization criteria:**

The following clinical information will be required for reauthorization:

1. Patient has been compliant on therapy including low-fat diet and exercise regimen
2. No contraindications to therapy
3. Patient has had at least a 50% sustained reduction in LDL-C levels from baseline

### **Reauthorization for 12 months**

Last reviewed/updated: 11/2015



**Juxtapid® (lomitapide ) Prior  
Authorization criteria Drug  
Protocol Management**

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**Juxtapid® (lomitapide) is a limited distribution specialty product ; dispensing is available through Dohmen Life Science Services . A quantity limit of 28 capsules per 28 days applies.**

**How do I obtain a prior authorization for Juxtapid®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnosis**

- Homozygous familial hypercholesterolemia (HoFH)

**Approval Criteria**

- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND**
  - Patient is  $\geq 18$  years of age **AND**
  - Patient is new to NHP and has already been started and stabilized on Juxtapid®
- OR**
- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND**
  - Patient is  $\geq 18$  years of age **AND**
  - Prescriber is a lipid specialist **AND**
  - Patient is adherent to a low-fat diet ( $< 20\%$  of energy supplied by dietary fat intake) and will be taking a dietary supplement to prevent nutritional deficiencies **AND**
  - Patient has experienced a documented inadequate response or intolerance to treatment with a high potency HMG Co-A reductase inhibitor (aka statin), including atorvastatin or rosuvastatin used in combination with ezetimibe, a fibric acid derivative, and/or cholestyramine **AND**
  - Patient has experienced an inadequate response or has a contraindication to lipid apheresis therapy **AND**
  - Patient has experienced an inadequate response or intolerance to Kynamro® (mipomersen)\* therapy **AND**
  - If female, patient has had a negative pregnancy test prior to initiation of treatment

\*Note: needle phobia is considered inadequate justification for not utilizing Kynamro®

**References**

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**Kalydeco® (ivacaftor) Prior  
Authorization Criteria Drug  
Protocol Management**

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**Kalydeco® (ivacaftor) tablets and oral granules are specialty products; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 60 tablets per 30 days applies to the tablet formulation.**

**How do I obtain a prior authorization for Kalydeco®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnosis**

- Treatment of cystic fibrosis (CF) in patients who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H.

**Approval Criteria**

- Patient is  $\geq 2$  years of age **AND**
- Patient has a diagnosis of cystic fibrosis **AND**
- Patient has documentation of one of the CFTR gene mutations for which Kalydeco® therapy is approved (as noted above)

**References**

- Kalydeco [package insert]. Boston (MA): Vertex Pharmaceuticals Inc.; 2015 Mar.
- U.S. Food and Drug Administration Approves Kalydeco (ivacaftor) for use in eight additional mutations that cause cystic fibrosis [press release on the internet]. Boston (MA): Vertex Pharmaceuticals Inc.; 14 Dec 2014. Available at: <http://www.vrtx.com/>
- U.S. Food and Drug Administration Approves Kalydeco (ivacaftor) for use in people with cystic fibrosis ages 6 and older who have the R117H mutation [press release on the internet]. Vertex Pharmaceuticals, Inc.; 21 Feb 2014. Available at: <http://www.vrtx.com/>
- Vertex Receives U.S. Food and Drug Administration Approval of Kalydeco® (ivacaftor) for Children with Cystic Fibrosis Ages 2 to 5 who have Specific Mutations in the CFTR Gene [press release on the internet]. Vertex Pharmaceuticals, Inc.; 18 Mar 2015. Available at: <http://www.vrtx.com/>

Last reviewed/updated: 4/6/15



**Kineret® (anakinra) Prior  
Authorization criteria Drug  
Protocol Management**

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**Kineret® (anakinra) is a specialty product; dispensing is available via BriovaRx specialty pharmacy.**

**How do I obtain a prior authorization for Kineret®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Moderately to severely active rheumatoid arthritis (RA)
- Cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), and neonatal onset multi-system inflammatory disorder (NOMID; also known as chronic infantile neurological cutaneous and articular [CINCA] syndrome)

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Kineret® for an approvable indication

**OR**

- Patient is  $\geq 18$  years of age **AND**
- Patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) **AND**
- Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD\*, if methotrexate is contraindicated) \*† **AND**
- Patient has experienced an inadequate response or intolerance to treatment with a tumor necrosis factor (TNF) blocking agent\*\* (unless medical rationale is presented as to why treatment with a TNF blocking agent is contraindicated)

**OR**

- Patient has a diagnosis of cryopyrin associated periodic syndromes (CAPS) **AND**
- Kineret® is being prescribed by a specialist or in consultation with a specialist (e.g., an immunologist, allergist, dermatologist, rheumatologist, neurologist, etc.)

\* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

\*† Methotrexate/DMARD trial requirement may be overridden for RA patients with documented high disease activity (advanced disease) with features of a poor prognosis (i.e., functional limitations, extra-articular disease, positive rheumatoid factor, or anti-cyclic citrullinated peptide antibodies, & bony erosions by radiograph)

\*\* TNF blocking agents include etanercept (Enbrel®), adalimumab (Humira®), certolizumab (Cimzia®), infliximab (Remicade®), & golimumab (Simponi®/Simponi Aria®)

Initial approvals may be issued for up to 6 months.

**Reauthorization Criteria**

- Improvement per physician assessment of overall disease activity

Reauthorizations may be granted for up to 12 months.



## References

- O' Dell JR. Therapeutic Strategies for Rheumatoid Arthritis. NEJM 2004; 350 (25): 2591-2602.
- Abramowicz M (ed.) Treatment Guidelines. The Medical Letter 2003; 5: 25-32.
- Kineret® [package insert]. Thousand Oaks (CA): Biovitrum; 2013 Oct.
- Saag KG, Teng GG, Patkar NM, Anuntiyo J, Finney C, Curtis JR, et al. American College of Rheumatology 2008: Recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis & Rheumatism (Arthritis Care & Research). 2008;59(6):762-784.
- Singh JA, Furst DE, Bharat A, Curtis JR, Kavanaugh AE, Kremer JM, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39.
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Last reviewed/updated: 4/6/15



**Korlym<sup>®</sup> (mifepristone)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Korlym<sup>®</sup> is a limited distribution specialty product; dispensing is available via Centric Specialty pharmacy. A quantity limit of 4 tablets per day applies.**

**How do I obtain a prior authorization for Korlym<sup>®</sup>?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approval Criteria for Korlym<sup>®</sup>**

- The member is new to NHP and has been stabilized on Korlym<sup>®</sup> for the approvable indication

**OR**

- The member has a diagnosis of endogenous Cushing's syndrome with concomitant Diabetes Type 2 or glucose intolerance **AND**
- The member has hyperglycemia secondary to hypercortisolism **AND**
- The member has failed or is not a candidate for corrective surgery or radiotherapy **AND**
- The member has had a documented side effect, allergy, inadequate response, or treatment failure with two adrenolytic therapies (e.g., ketoconazole, metyrapone, mitotane, etomidate), one of which must be ketoconazole **AND**
- There are no known contraindications to the use of Korlym<sup>®</sup> (i.e., pregnancy, required concomitant therapy with systemic corticosteroids for a documented medical condition, unexplained vaginal bleeding, endometrial changes [i.e., endometrial hyperplasia with atypia or endometrial carcinoma, drug interactions, etc.]

Initial approval will be for 6 months

**Reauthorization criteria**

- Documentation of effectiveness, as evidenced by control of hyperglycemia and improvement in signs and symptoms.
- Reauthorizations may be granted for a duration of 6 months

**References**

- Korlym<sup>®</sup> [package insert]. Menlo Park (CA): Corcept Therapeutics, Inc.; 2013 Jun.
  - Corcept Therapeutics Incorporated announces FDA approval of Korlym<sup>®</sup> (mifepristone) 300 mg tablets: first and only approved medication for Cushing's syndrome patients. February 17, 2012. Available at: [http://www.corcept.com/news\\_events/view/pr\\_1329524335](http://www.corcept.com/news_events/view/pr_1329524335). Accessed 2014 Aug 15.
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- Last reviewed/updated: 11/10/14



**Krystexxa® (pegloticase)  
Prior Authorization criteria  
Drug Protocol Management**

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**Krystexxa® (pegloticase) is a limited distribution specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 2 vials per 28 days applies.**

**How do I obtain a prior authorization for Krystexxa®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Chronic gout refractory to conventional therapies
- Tophaceous gout (chronic gout with the presence of tophi)

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Krystexxa® for an approvable diagnosis  
**OR**
- Patient has a diagnosis of gout with documentation or evidence of tophi present  
**OR**
- Patient has a diagnosis of chronic gout **AND**
- Patient has a documented side-effect, allergy, therapy failure, or contraindication to treatment with allopurinol (dose maximization required based upon patient's renal function) **AND**
- Patient has a documented side-effect, allergy, therapy failure, or contraindication to treatment with febuxostat (Uloric®)

All other indications will be evaluated on a case-by case basis

Initial authorizations will be for the duration of treatment requested, up to a maximum of 6 months.

**Reauthorization Criteria**

- Improvement per physician assessment/evaluation of overall disease activity, including improvement in gout attacks and symptomology

Reauthorizations will be for a duration of 6 months.

**References**

- Krystexxa® [package insert]. East Brunswick (NJ): Savient Pharmaceuticals Inc.; 2014 Jan.
- Krystexxa (pegloticase) for intravenous infusion. Briefing Document for Arthritis Advisory Committee Division of Anesthesia, Analgesia, and Rheumatology Products: BLA No. 125293. Rockville (MD): Food and Drug Administration; 2009 Jun. Available at: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisDrugsAdvisoryCommittee/UCM165814.pdf>.
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**Kynamro<sup>®</sup> (mipomersen sodium)**  
**Prior Authorization criteria Drug**  
**Protocol Management**

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**Kynamro<sup>®</sup> (mipomersen sodium) is a limited distribution specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 4 syringes per 28 days applies.**

**How do I obtain a prior authorization for Kynamro<sup>®</sup>?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnosis**

- Homozygous familial hypercholesterolemia (HoFH)

**Approval Criteria**

- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND**
- Patient is  $\geq 18$  years of age **AND**
- Patient is new to NHP and has already been started and stabilized on Kynamro<sup>®</sup>  
**OR**
- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND**
- Patient is  $\geq 18$  years of age **AND**
- Patient is adherent to a low-fat diet ( $< 20\%$  of energy supplied by dietary fat intake) **AND**
- Patient has had a documented side-effect, allergy, inadequate response, treatment failure, or contraindication to treatment with a high potency HMG Co-A reductase inhibitor (e.g. statin), including atorvastatin or rosuvastatin used in combination with ezetimibe, a fibric acid derivative, and/or cholestyramine **AND**
- Patient has had an inadequate response, treatment failure, or has a contraindication to lipid apheresis therapy **AND**
- If female, patient has had a negative pregnancy test prior to initiation of treatment with Kynamro<sup>®</sup>

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Last reviewed/updated: 1/12/15



**Lemtrada<sup>®</sup> (alemtuzumab)  
Prior Authorization criteria  
Drug Protocol Management**

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**Lemtrada<sup>®</sup> (alemtuzumab) is a limited distribution specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 5 vials per 365 days and 8 vials per lifetime applies.**

**How do I obtain a prior authorization for Lemtrada<sup>®</sup>?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnosis**

- Relapsing multiple sclerosis (MS)

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Lemtrada<sup>®</sup> for the approvable indication  
**OR**
- Patient has a diagnosis of a relapsing form of multiple sclerosis (MS) **AND**
- Patient is  $\geq 18$  years of age **AND**
- Prescribing physician is a neurologist or MS specialist **AND**
- Requested dosing regimen does not exceed the FDA-approved dosing regimen with respect to dose, frequency, and treatment duration **AND**
- Patient has experienced an inadequate response or intolerance to at least three (3) of the following:
  - interferon therapy (Rebif<sup>®</sup>, Avonex<sup>®</sup>, Betaseron<sup>®</sup>, Extavia<sup>®</sup>, Plegridy<sup>®</sup>, etc.)\*
  - glatiramer acetate (Copaxone<sup>®</sup>)\*
  - dimethyl fumarate (Tecfidera<sup>®</sup>)
  - teriflunomide (Aubagio<sup>®</sup>)
  - fingolimod (Gilenya<sup>®</sup>)

\*Note: needle phobia is considered inadequate justification for not utilizing a self-administered injectable product

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**Omega-3-acid ethyl esters (Lovaza®) & Vascepa® (icosapent ethyl)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Omega-3-acid ethyl esters (Lovaza®) and Vascepa® (icosapent ethyl)**

- **Quantity Limit: 120 capsules/30 days**

**How do I obtain a prior authorization for omega-3-acid ethyl esters (Lovaza®) or Vascepa®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Severe hypertriglyceridemia ( $\geq 500$  mg/dL)

**Approval Criteria: omega-3-acid ethyl esters (Lovaza®)**

- Patient is new to NHP and has been stabilized on omega-3-acid ethyl esters (Lovaza®) for the approvable indication

**OR**

- Patient has had a documented side effect, allergy, or treatment failure with **a minimum of one agent from each of the following categories:**
  - Fibric acid derivatives (e.g. fenofibrate, gemfibrozil, etc.)
  - Long-acting niacin agents (e.g. niacin ER, Niaspan®, Simcor®, Advicor®, etc.)
  - HMG-CoA reductase inhibitors (aka "Statins": simvastatin, atorvastatin, rosuvastatin, etc.)

Approvals will be for a duration of 3 years (36 months).

**Approval Criteria: Vascepa®**

- Patient is new to NHP and has been stabilized on Vascepa® for the approvable indication

**OR**

- Patient has had a documented side effect, allergy, or treatment failure with **a minimum of one agent from each of the following categories:**
  - Fibric acid derivatives (e.g. fenofibrate, gemfibrozil, etc.)
  - Long-acting niacin agents (e.g. niacin ER, Niaspan®, Simcor®, Advicor®, etc.)
  - HMG-CoA reductase inhibitors (aka "Statins": simvastatin, atorvastatin, rosuvastatin, etc.)

**AND**

- Patient has had a documented side effect, allergy, or treatment failure with omega-3-acid ethyl esters (Lovaza®)

Approvals will be for a duration of 3 years (36 months).

**References**

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Last reviewed/updated: 8/3/15



**Makena<sup>®</sup> (hydroxyprogesterone caproate)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Makena<sup>®</sup> (hydroxyprogesterone caproate) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. The maximum approvable quantity is 21 doses.**

**How do I obtain a prior authorization for Makena<sup>®</sup>?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnosis**

- Prevention of pre-term labor during a singleton pregnancy

**Approval Criteria**

- The member must currently have a singleton pregnancy
- AND**
- The member must have a history of spontaneous singleton delivery before 37 weeks of gestation
- AND**
- The member must be between 16 weeks zero days and 20 weeks, six days gestation

**References**

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Last reviewed/updated: 7/1/14



**Neupro™ (rotigotine transdermal system)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Neupro™ (rotigotine transdermal system)**

- **Quantity limit: 30 patches/30 days**

**How do I obtain a prior authorization for Neupro™?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Idiopathic Parkinson's disease (IPD)
- Restless Legs Syndrome (RLS)

**Approval Criteria**

- Patient has a diagnosis of either IPD or RLS **AND**
  - Patient has tried an oral dopamine agonist [e.g. bromocriptine (Parlodel®), pramipexole (Mirapex®), ropinirole (Requip®), etc.] and experienced compliance difficulties
- OR**
- Patient has a diagnosis of either IPD or RLS **AND**
  - Patient has a documented inability to swallow tablets

Approvals will be for a duration of 3 years (36 months).

**References**

- Neupro® [package insert]. Smyrna (GA): UCB, Inc.; 2013 Sep.
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**Noxafil® (posaconazole)  
Prior Authorization Criteria  
Drug Protocol Management**

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**How do I obtain a prior authorization for Noxafil®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Prophylaxis of invasive *Aspergillus* fungal infections
- Prophylaxis of invasive *Candida* fungal infections
- Treatment of oropharyngeal candidiasis (oral thrush – oral suspension only)

**Approval criteria**

- The diagnosis is prevention of an invasive *Aspergillus* or *Candida* fungal infection **AND**
- The patient has had documented inadequate response, adverse reaction, or contraindication to voriconazole (Vfend®)\*

**OR**

- The diagnosis is treatment of oropharyngeal candidiasis (oral thrush) **AND**
- The patient has had documented inadequate response, adverse reaction, or contraindication to both voriconazole (Vfend®) and high-dose fluconazole\* **AND**
- The requested medication is Noxafil® oral suspension

\* Voriconazole (Vfend®) and high-dose fluconazole trials will not be required when the prescriber of Noxafil® is an infectious disease (ID) specialist or a hematology/oncology specialist

Approvals will be for a duration of 3 months.

**References**

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  - Walsh TJ, Anaissie EJ, Denning DW, Herbrecht R, Kontoyiannis DP, Marr KA, et al. Treatment of aspergillosis: Clinical practice guidelines of the Infectious Diseases Society of America. Clin Infect Dis. 2008;46(3):327-60.
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- Last reviewed/update: 1/12/15



**Nuedexta® (dextromethorphan hydrobromide/quinidine sulfate)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Nuedexta® (dextromethorphan hydrobromide/quinidine sulfate)**

- **Quantity Limit: 60 capsules/30 days**

**How do I obtain a prior authorization for Nuedexta®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Pseudobulbar affect (PBA) due to a neurological condition

**Approval Criteria**

- Patient has a diagnosis of pseudobulbar affect (PBA) due to a neurological condition **AND**
- Patient does not have any contraindications to use of Nuedexta®, including the following:
  - Concomitant use with quinidine, quinine, or mefloquine
  - History of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions
  - Known hypersensitivity to dextromethorphan
  - Concomitant use with a monoamine oxidase inhibitor (MAOI) or within 14 days of stopping an MAOI
  - Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure
  - Complete atrioventricular (AV) block without implanted pacemaker, or patients at high risk of complete AV block
  - Concomitant use with drugs that both prolong the QT interval and are metabolized by CYP2D6 (e.g. thioridazine, pimozide, etc.)

Approvals will be for a duration of 1 year (12 months).

**References**

- Nuedexta® [package insert]. Aliso Viejo (CA): Avanir Pharmaceuticals, Inc.; 2013 Dec.
- The Medical Letter, Inc. Dextromethorphan/quinidine (Nuedexta) for pseudobulbar affect. Med Lett Drugs Ther. 2011 Jun 13;53(1366):46-7.
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**Oral Anticoagulants Prior  
Authorization Criteria Drug  
Protocol Management**

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**Eliquis<sup>®</sup> (apixaban), Pradaxa<sup>®</sup> (dabigatran), Xarelto<sup>®</sup> (rivaroxaban)**

- **Quantity Limit**
  - **Eliquis<sup>®</sup> (apixaban): 60 tablets/30 days**
  - **Pradaxa<sup>®</sup> (dabigatran): 60 capsules/30 days**
  - **Xarelto<sup>®</sup> (rivaroxaban)**
    - **Starter Pack: 1 pack (51 tablets)/30 days; 1 fill per lifetime**
    - **10 mg: 35 tablets/35 days; 1 fill per 365 days (no prior authorization required within quantity limit)**
    - **15 mg: 42 tablets/21 days**
    - **20 mg: 30 tablets/30 days**

**How do I obtain a prior authorization for an oral anticoagulant?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approval Criteria for Eliquis<sup>®</sup> (apixaban) 2.5 mg and 5 mg tablets**

- Product is being used for **one** of the following indications:
  - Prevention of stroke and embolism in patients with atrial fibrillation (AF)
  - Prevention of deep vein thrombosis (DVT) following knee or hip replacement surgery
- AND**
- Dosage prescribed is within the FDA-approved dosage range for the given indication.

Approval duration is based on indication for use as follows:

- Prevention of stroke and embolism in patients with AF: 36 months
- Prevention of DVT following knee replacement surgery: 12 days
- Prevention of DVT following hip replacement surgery: 35 days

**Approval Criteria for Pradaxa<sup>®</sup> (dabigatran) 75 mg and 150 mg capsules**

- Product is being used for one of the following indications:
  - Prevention of stroke and embolism in patients with atrial fibrillation
  - Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)
  - Reduction in the risk of DVT and PE recurrence
- AND**
- Dosage prescribed is within the FDA-approved dosage range for the given indication.

Approvals will be for a duration of 36 months.

**Approval Criteria for Xarelto<sup>®</sup> (rivaroxaban) 15 mg and 20 mg tablets**

- Product is being used for one of the following indications:
  - Prevention of stroke and embolism in patients with atrial fibrillation
  - Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)
  - Reduction in the risk of DVT and PE recurrence
- AND**



- Dosage prescribed is within the FDA-approved dosage range for the given indication.

Approval duration is based on indication for use as follows:

- Prevention of stroke and embolism in patients with AF: 36 months
- Treatment of DVT or PE: 12 months
- Reduction in the risk of DVT and PE recurrence: 12 months

**\*\*Note\*\*:** Use of the Xarelto 10mg tablets for the prevention of DVT following knee or hip replacement surgery is covered without a prior authorization; quantity limits apply.

## References

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Last reviewed/updated: 12/10/14



**Oravig<sup>®</sup> (miconazole) buccal tablets**  
**Prior Authorization Criteria Drug**  
**Protocol Management**

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**Oravig<sup>®</sup> (miconazole) 50 mg buccal tablets**

**How do I obtain a prior authorization for Oravig<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approval Diagnoses:**

- Treatment of oropharyngeal candidiasis

**Approval Criteria:**

- The member has a documented side effect, allergy, or treatment failure to each of the following treatment agents:
  - o clotrimazole troches/lozenges
  - o oral nystatin suspension
  - o generic fluconazole tablets

All other indications will be evaluated on a case-by case basis.

Last reviewed/updated: 6/9/14



## **Orencia® (abatacept) Prior Authorization criteria Drug Protocol Management**

**Orencia® (abatacept) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

### **How do I obtain a prior authorization for Orencia®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

### **Approvable Diagnoses**

- Moderately to severely active rheumatoid arthritis (RA)
- Juvenile idiopathic arthritis (JIA)

### **Approval Criteria**

- Patient is new to NHP and has been stabilized on Orencia® for an approvable indication

#### **OR**

- Patient is  $\geq 18$  years of age **AND**
- Patient has a diagnosis of moderately to severely active rheumatoid arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with at least one (1) DMARD\* **OR** at least one (1) tumor necrosis factor (TNF) blocking agent\*\*

#### **OR**

- Patient is between 6 and 17 years of age **AND**
- Patient has a diagnosis of juvenile idiopathic arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with the recommended initial and continued therapies (please refer to Appendices 1 & 2 below)

\* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

\*\* TNF blocking agents include etanercept (Enbrel®), adalimumab (Humira®), certolizumab (Cimzia®), infliximab (Remicade®), & golimumab (Simponi®/Simponi Aria®)

Initial approvals may be issued for up to 6 months.

### **Reauthorization Criteria**

- Improvement per physician assessment of overall disease activity

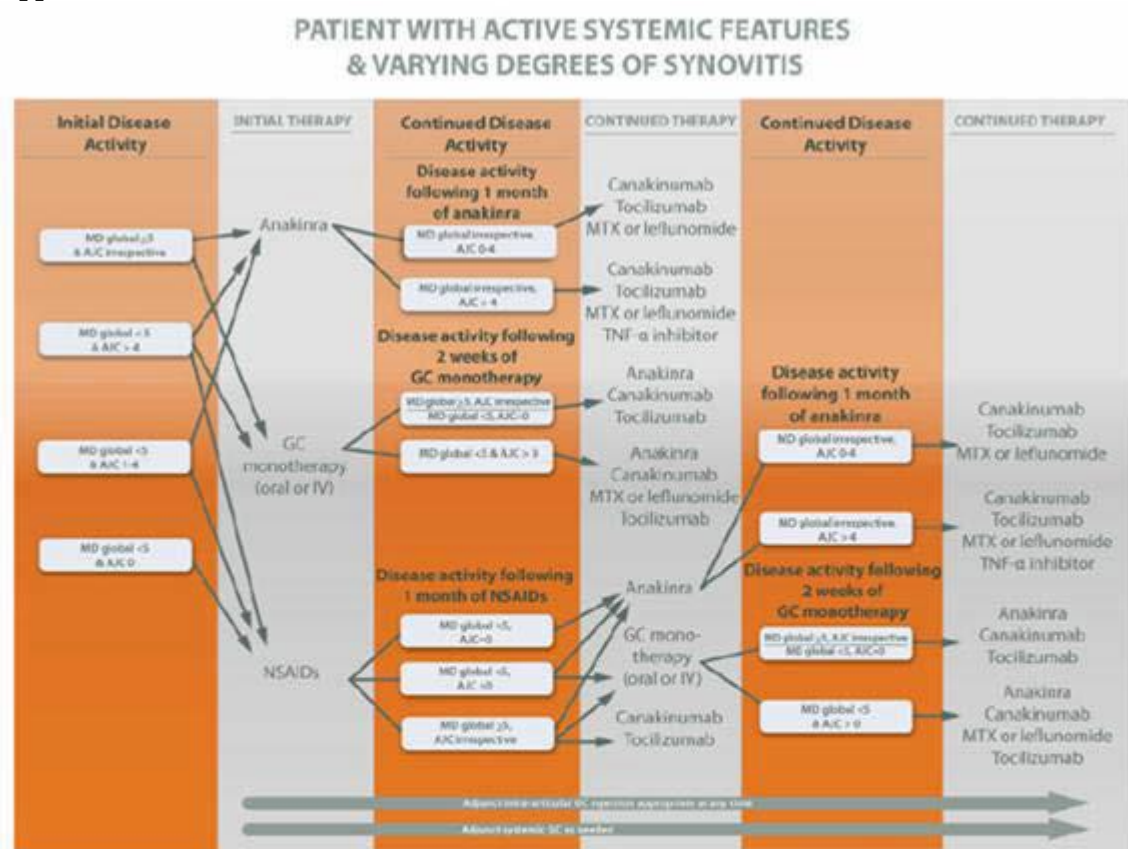
Reauthorizations may be granted for up to 12 months.

### **References**

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## Appendix 1

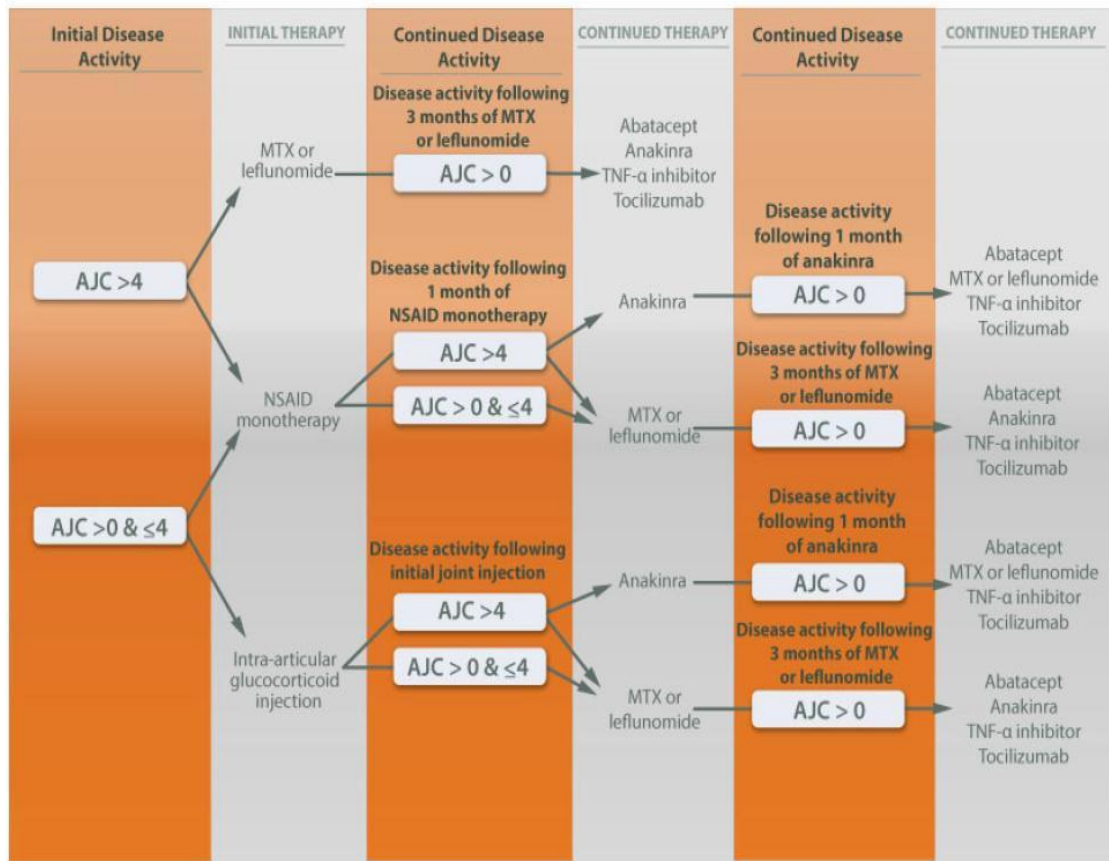


**Figure 1.** Treatment pathways for patients with active systemic features and varying degrees of synovitis. The Task Force Panel was asked to consider the treatments among patients with active systemic features and a physician global assessment (MD global) of  $\leq 5$  or  $\geq 5$  on a 10-point numerical rating scale (0–10 visual analog scale, where 0 = no disease activity and 10 = the most severe) and by active joint count (AJC; 0 joints, 1–4 joints, or  $\geq 5$  joints). If a recommendation is noted to be irrespective of the AJC or MD global, the recommendation was for children with an AJC  $\geq 0$  or an MD global  $\geq 0$ , respectively. Adjunct systemic glucocorticoids (GCs) and/or intraarticular GCs may be added at any point. Children may qualify for  $>1$  pathway, in which case it is left to the provider's discretion to choose the path they feel is most appropriate based upon specific patient characteristics and/or patient and family preferences. Steps in the progression of therapy can be additive or sequential, except that therapies with a biologic agent are sequential [combination therapy with a biologic agent is not endorsed]. The recommendations in this figure are for patients with active systemic features. If the systemic features (but not the arthritis) respond to therapy, then subsequent treatment decisions should be based upon the recommendations in Figure 2. NSAIDs = nonsteroidal antiinflammatory drugs; IV = intravenous; MTX = methotrexate; TNF $\alpha$  = tumor necrosis factor  $\alpha$ .

Source: *Arthritis & Rheumatism*. 2013;65(10):2499-2512

## Appendix 2

### PATIENT WITHOUT ACTIVE SYSTEMIC FEATURES & VARYING DEGREES OF SYNOVITIS



**Figure 2.** Treatment pathways for patients without active systemic features and with varying degrees of synovitis. The Task Force Panel was asked to rate the appropriateness of therapies based on the total number of active joints ( $\leq 4$  or  $> 4$ ). Children may qualify for  $> 1$  pathway, in which case it is left to the provider's discretion to choose the path they feel is most appropriate based upon specific patient characteristics and/or patient and family preferences. Steps in the progression of therapy can be additive or sequential, except that therapies with a biologic agent are sequential (combination therapy with a biologic agent is not endorsed). AJC = active joint count; MTX = methotrexate; NSAID = nonsteroidal antiinflammatory drug; IV = intravenous; TNF $\alpha$  = tumor necrosis factor  $\alpha$ .

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512



**Orkambi®  
(lumacaftor/ivacaftor) Prior  
Authorization Criteria Drug  
Protocol Management**

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**I. Indications**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Treatment of cystic fibrosis (CF) in patients age 6 years and older who are homozygous for the F508del mutation in the CFTR gene.

*Limitations of use:* The efficacy and safety of Orkambi have not established in patients with CF other than those homozygous for the F508del mutation.

All other indications are considered experimental/investigational and are not a covered benefit.

**II. Required Documentation**

The following information is necessary to initiate the prior authorization review: Results of genetic testing positive for the F508del mutation on both alleles of the CFTR gene.

**III. Criteria for Initial Approval**

**A. Cystic Fibrosis**

Indefinite authorization may be granted for treatment of cystic fibrosis when all of the following criteria are met:

1. Genetic testing was conducted to detect a mutation in the CFTR gene.
2. The member is positive for the F508del mutation on both alleles of the CFTR gene.
3. The member is at least 6 years of age.
4. Orkambi will not be used in combination with Kalydeco.

**IV. Continuation of Therapy**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**V. Dosage and Administration**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**VI. References**

1. Orkambi [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.' September





## **Otezla<sup>®</sup> (apremilast) Prior Authorization Criteria Drug Protocol Management**

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Otezla<sup>®</sup> (apremilast) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 60 tablets per 30 days applies to the 30 mg strength tablets; combination strength dose titration packs are subject to a quantity limit of 1 pack per lifetime.

### **How do I obtain a prior authorization for Otezla<sup>®</sup>?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

### **Approvable Diagnoses**

- Psoriatic arthritis
- Moderate to severe chronic plaque psoriasis

### **Approval Criteria**

- Patient is new to NHP and has been stabilized on Otezla<sup>®</sup> for an approvable indication

#### **OR**

- Patient is  $\geq 18$  years if age **AND**
- Patient has a diagnosis of psoriatic arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD<sup>†</sup>, if methotrexate is contraindicated)<sup>\*†</sup> **AND**
- Patient has experienced an inadequate response or intolerance to treatment with a tumor necrosis factor (TNF) blocking agent (unless medical rationale is presented as to why treatment with a TNF blocking agent is contraindicated)

#### **OR**

- Patient is  $\geq 18$  years if age **AND**
- Patient has a diagnosis of moderate to severe chronic plaque psoriasis affecting  $\geq 10\%$  body surface area **AND**
- Patient has experienced an inadequate response or intolerance to at least **one (1)** agent from at least **two (2)** of the following **three (3)** categories:
  - **Topical agents:** emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene
  - **Systemic agents:** methotrexate, sulfasalazine, cyclosporine, tacrolimus, acitretin, mycophenolate mofetil, azathioprine, hydroxyurea, etc.
  - **Phototherapy:** ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB), etc.

<sup>†</sup> Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

<sup>\*†</sup> Methotrexate/DMARD trial requirement may be overridden for patients with documented axial disease whose condition is not adequately controlled with NSAIDs

Initial approvals may be issued for up to 6 months for psoriatic arthritis and up to 3 months for plaque psoriasis.

## Reauthorization Criteria

- Improvement per physician assessment of overall disease activity

Reauthorizations will be for a duration of 12 months for psoriatic arthritis and 6 months for plaque psoriasis.

## References

- American Academy of Dermatology. Position Statement on Treatment of Psoriatic Patients. April 27, 2013. Available at: <http://www.aad.org/Forms/Policies/Uploads/PS/PS%20on%20Treatment%20of%20Psoriatic%20Patients.pdf>. Accessed March 31, 2014.
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Last reviewed/updated: 4/6/15





**Oxtellar XR™ (oxcarbazepine extended release) Prior  
Authorization Criteria  
Drug Protocol Management**

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**Oxtellar XR™ (oxcarbazepine ER)**

- **Quantity Limit**
  - **150 mg & 300 mg strengths: 30 tablets/30 days if approved**
  - **600 mg strength: 120 tablets/30 days if approved**

**How do I obtain a prior authorization for Oxtellar XR™?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Epilepsy (seizures)

**Approval criteria**

- Patient is a new NHP member and has already been stabilized on Oxtellar XR™ for an approvable diagnosis
- OR**
- The diagnosis is epilepsy and the member has had previous medication trials of 2 anticonvulsants, one of which was generic regular-release oxcarbazepine (tablets or suspension).

Approvals will be for a duration of 3 years (36 months).

**References**

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Last reviewed/updated: 4/6/15



## **Prolia<sup>®</sup> (denosumab) Prior Authorization Criteria Drug Protocol Management**

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**Prolia<sup>®</sup> (denosumab) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 1 syringe per 180 days applies.**

### **How do I obtain a prior authorization for Prolia<sup>®</sup>?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

### **Approvable Diagnoses**

- Osteoporosis in postmenopausal women
- Osteoporosis in men
- Bone loss in men receiving androgen deprivation therapy for prostate cancer
- Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer

### **Approval Criteria**

- Patient is new to NHP and has been stabilized on Prolia<sup>®</sup> for an approvable indication  
**OR**
- Patient has one of the approvable diagnoses listed above **AND**
- Patient is at high risk for fracture, defined as having a history of osteoporotic fracture or the existence of multiple risk factors for fracture **AND**
- Patient has experienced an intolerance or inadequate response to treatment with a preferred bisphosphonate (unless bisphosphonate therapy is medically contraindicated)<sup>†</sup> **AND**
- Patient will continue to receive daily calcium and vitamin D therapies

<sup>†</sup> Bisphosphonates used in the treatment of osteoporosis (subject to step therapy rules) include alendronate (Fosamax<sup>®</sup>), ibandronate (Boniva<sup>®</sup>), risedronate (Actonel<sup>®</sup>; Atelvia<sup>®</sup>), & zoledronic acid (Reclast<sup>®</sup>)

Initial approvals may be issued for up to 2 years.

### **Reauthorization Criteria**

- Documented response to therapy based on physician assessment (e.g., improvement in bone mineral density, treatment tolerability, and/or lack of bone fracture while on therapy)

Reauthorizations may be granted for up to 2 years.

### **References**

- Prolia<sup>®</sup> [package insert]. Thousand Oaks (CA); Amgen Inc.; 2014 Jun.
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**Promacta<sup>®</sup> (eltrombopag)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Promacta<sup>®</sup> (eltrombopag) is a limited distribution specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. The following diagnosis-specific quantity limits apply:**

- **For chronic ITP and thrombocytopenia in chronic hepatitis C:** 30 tablets per 30 days (12.5 mg, 25 mg, and 75 mg strengths); 60 tablets per 30 days (50 mg strength)
- **For severe aplastic anemia:** 30 tablets per 30 days (12.5 mg, 25 mg, 50 mg strengths); 60 tablets per 30 days (75 mg strength)

**How do I obtain a prior authorization for Promacta<sup>®</sup>?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approval Diagnosis:**

- Chronic immune thrombocytopenia purpura (ITP)
- TCP in patients with chronic hepatitis C to allow for initiation & maintenance of interferon-based therapy
- Severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy.

**Approval Criteria:**

- The patient is a new NHP member and has already been stabilized on Promacta<sup>®</sup> for an approvable diagnosis  
**OR**

- The patient has a diagnosis of chronic ITP **AND**
- The patient had a documented treatment failure with corticosteroids or immunoglobulins; **OR** is status-post splenectomy  
**OR**

- The patient has a diagnosis of thrombocytopenia and chronic hepatitis C **AND**
- The patient will initiate interferon-based therapy<sup>†</sup> and current platelet count is  $\leq 75,000$  cells/mm<sup>3</sup> **OR**
- The patient has already initiated and is stable on Promacta<sup>®</sup> therapy and the current platelet count supports the continued use of Promacta<sup>®</sup> (per prescribing information)\* <sup>†</sup> **AND**
- The patient requires continued antiviral therapy for the management of chronic hepatitis C<sup>†</sup>

\* Note: In clinical trials patients were treated with Promacta<sup>®</sup> to a threshold platelet level of  $\geq 90 \times 10^9/L$ .

<sup>†</sup> Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection. **OR**

- The patient has a diagnosis of severe aplastic anemia **AND**

- The patient had a documented inadequate response with immunosuppressive therapy (e.g., anti-thymocyte globulin, cyclosporin, steroids, etc.)

All other indications will be evaluated on a case-by case basis.

### **Initial authorizations:**

Chronic immune thrombocytopenia purpura (ITP) or thrombocytopenia in chronic hepatitis C

- May be issued for duration of treatment requested, up to 3 months
- Quantity limit: 30 tablets per 30 days (12.5mg, 25mg, 75mg strengths)  
60 tablets per 30 days (50mg strength)

Severe aplastic anemia

- May be issued for duration of treatment requested, up to 4 months
- Quantity limit: 30 tablets per 30 days (12.5mg, 25mg, 50mg strengths)  
60 tablets per 30 days (75mg strength)

### **Recertification Criteria:**

Chronic immune thrombocytopenia purpura (ITP):

- Improvement per physician assessment/evaluation of overall disease, including improvement in platelet counts
  - Reauthorizations may be granted for up to 1 year

Thrombocytopenia in patients with chronic hepatitis C:

- Improvement in platelet counts (levels not to exceed  $400 \times 10^9/L$ )
  - Reauthorizations may be granted for requested duration up to 3 months, provided the request does not exceed the duration of antiviral therapy (including futility rules with pegylated interferon and protease inhibitor triple therapy).

Severe aplastic anemia:

- Improvement per physician assessment/evaluation of overall disease, including improvement in platelet counts to achieve the target range of  $\geq 50 \times 10^9/L$  as necessary.
- If no hematologic response (i.e., RBCs, WBCs, and/or platelets) has occurred after 16 weeks of therapy will not be reauthorized. Therapy should also be discontinued if new cytogenic abnormalities are observed.
- For patients who achieve tri-lineage response, including transfusion independence, lasting at least 8 weeks: the dose may be reduced by 50%. If counts remain stable after 8 weeks at the reduced dose, then discontinue treatment and monitor blood counts. If subsequent platelet counts drop to less than  $30 \times 10^9/L$ , hemoglobin to less than 9 g/dL, or ANC to less than  $0.5 \times 10^9/L$ , reinstitute treatment at the previous effective dose.
  - Reauthorizations may be granted for up to 1 year

## **Recommended Dosage:**

### **Chronic immune thrombocytopenia purpura (ITP):**

- Initiation: 50 mg once daily (Note: Patients of East Asian ancestry or patients with moderate to severe hepatic insufficiency should be started at 25 mg daily; Patients of East Asian ancestry and hepatic impairment, consider initiating at a reduced dose of 12.5 mg daily)
- Daily dose should be adjusted to achieve & maintain a platelet count  $\geq 50 \times 10^9/L$  to reduce the risk of bleeding
- Maximum daily dose: 75 mg

### **Thrombocytopenia in patients with chronic hepatitis C:**

- Initiation: 25 mg once daily
- The dose should be adjusted in 25 mg increments every 2 weeks as needed to achieve the target platelet count required for initiation of antiviral therapy. Monitor platelet counts weekly prior to initiating antiviral therapy.
- During antiviral therapy management for hepatitis C, adjust the dose of Promacta® to desired platelet level response to avoid dose reductions of pegylated interferon therapy.
- Maximum daily dose: 100 mg

### **Severe aplastic anemia:**

- Initial Dose Regimen: Initiate PROMACTA at a dose of 50 mg once daily.  
(Note: For severe aplastic anemia in patients of East Asian ancestry or patients with mild, moderate to severe hepatic impairment start therapy with 25 mg daily)
- The dose should be adjusted in 50 mg increments every 2 weeks as necessary to achieve the target platelet count  $\geq 50 \times 10^9/L$  as necessary.
- Monitor clinical hematology and liver tests regularly throughout treatment modify the dosage regimen based on platelet counts as outlined within the prescribing information.
- Maximum daily dose: 150 mg daily

## **Pharmacist's Notes:**

- Eltrombopag should be administered on an empty stomach (1 hour before or 2 hours after a meal).
- The agent should be discontinued if the platelet count does not increase to a level sufficient to avoid bleeding after 4 weeks of therapy at the maximum dose as well as in clinical situations where liver test abnormalities or excessive platelet count responses are reported.
- Use of products that inhibit the CYP1A2 and CYP2C8 enzymes will result in elevated eltrombopag levels.
  - CYP 1A2 inhibitors include: ciprofloxacin, fluvoxamine, mexiletine, propafenone, zileuton, etc.
  - CYP 2C8 inhibitors include gemfibrozil, trimethoprim, etc.
  - Since eltrombopag is an inhibitor of the organic anion transporting polypeptide (OATP1B1) it may potentially increase the exposure of other drugs that are substrates of this transporter (e.g., atorvastatin, fluvastatin, pravastatin, & MTX.
  - Eltrombopag has also been shown to chelate polyvalent cations in foods, mineral supplements, and antacids. Eltrombopag should be separated by 4 hours with any of these medications or products containing polyvalent cations (i.e., aluminum, calcium, iron, magnesium, selenium, and zinc) to avoid reduction in eltrombopag absorption.
- Excessive doses of eltrombopag can potentially increase platelet counts to levels that can produce thrombotic complications. As a result of this risk, caution should be used when this medication is administered to patients with known risk factors for thromboembolism; and this medication should not be used to normalize platelet counts.

- Clinical studies have not excluded a risk of bone marrow fibrosis with clinical consequences. If new or worsening blood morphological abnormalities or cytopenias occur, consider a bone marrow biopsy with staining for fibrosis.
- See manufacturer's prescribing information for dosing adjustments due to platelet counts.
- Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.
- Promacta® may cause hepatotoxicity. Promacta®, in combination with interferon and ribavirin in patients with chronic hepatitis C, may increase the risk of hepatic decompensation:
  - Measure serum ALT, AST, & bilirubin prior to initiating Promacta®, every 2 weeks during the dose adjustment phase & monthly following establishment of a stable dose. If bilirubin is elevated, perform fractionation.
  - Evaluate abnormal serum liver tests with repeat testing within 3 to 5 days. If confirmed, monitor serum liver tests weekly until the abnormalities resolve, stabilize, or return to baseline levels.
  - Discontinue Promacta® if ALT levels increase to  $\geq 3X$  the upper limit of normal (ULN) and are:
    - Progressive, or
    - Persistent for  $\geq 4$  weeks, or
    - Accompanied by increased direct bilirubin, or
    - Accompanied by clinical symptoms of liver injury or evidence for hepatic decompensation.
- Eltrombopag also carries a black box warning related to the risks of hepatotoxicity:

### **Black Box Warning for Eltrombopag**

#### **WARNING: RISK FOR HEPATOTOXICITY**

**In patients with chronic hepatitis C, Promacta® in combination with interferon and ribavirin may increase the risk of hepatic decompensation.**

### **References:**

- Promacta® [package insert]. North Carolina: GlaxoSmithKline; 2015 Apr.
- Bussel J, Cheng G, Mansoor N, Psaila B, Kovaleva L, Meddeb B et al. Eltrombopag for the treatment of chronic idiopathic thrombocytopenic purpura. *NEJM*. 2007;357(22):2237-47.
- Two New Drugs for Chronic ITP. *Med Lett Drugs Ther*. Feb 2009;51(1305): 10-11.
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- GSK receives FDA approval of an additional Promacta® (eltrombopag) indication for use in patients with severe aplastic anemia (SAA) who have had an insufficient response to immunosuppressive therapy (IST) [press release on the internet]. London, UK: GlaxoSmithKline; 2014 Aug 26 [cited 2015 May 21]. Available at: <http://us.gsk.com/en-us/media/press-releases/>
- Townsley DM, Desmond R, Dunbar CE, et al. "Pathophysiology and management of thrombocytopenia in bone marrow failure: possible clinical applications of TPO receptor agonists in aplastic anemia and myelodysplastic syndromes." *Int J Hematology*. 2013; 98(1):48-55.
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Last reviewed/updated:6/27/16



**Modafinil (Provigil®) and Nuvigil® (armodafinil)  
Prior Authorization Criteria  
Drug Protocol Management**

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**How do I obtain a prior authorization for modafinil or Nuvigil®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnoses**

- Narcolepsy
- Excessive sleepiness associated with either obstructive sleep apnea syndrome or hypopnea syndrome
- Attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD) [*modafinil only*]
- Fatigue associated with multiple sclerosis (MS) or chemotherapy [*modafinil only*]
- Excessive sleepiness associated with Parkinson's disease [*modafinil only*]

**Approval Criteria**

Modafinil (Provigil®)

- Patient has a diagnosis of narcolepsy and has failed therapy with at least one long-acting stimulant **OR**
- Patient has a diagnosis of excessive sleepiness associated with obstructive sleep apnea or hypopnea syndrome that has been confirmed by a sleep study, is currently using CPAP and being titrated, and has failed therapy with at least one long-acting stimulant **OR**
- Patient has a diagnosis of ADD or ADHD and has failed therapy with at least two long-acting stimulants and Strattera **OR**
- Patient has a diagnosis of fatigue associated with MS and has failed therapy with one formulary CNS stimulant or amantadine **OR**
- Patient has a diagnosis of fatigue associated with chemotherapy and has failed therapy with one formulary CNS stimulant **OR**
- Patient has a diagnosis of excessive sleepiness associated with Parkinson's disease and has failed therapy with at least one long-acting methylphenidate product

Nuvigil® (armodafinil)

- Patient has a diagnosis of narcolepsy and has failed therapy with at least one long-acting stimulant and modafinil **OR**
- Patient has a diagnosis of excessive sleepiness associated with obstructive sleep apnea or hypopnea syndrome that has been confirmed by a sleep study, is currently using CPAP and being titrated, and has failed therapy with at least one long-acting stimulant and modafinil

Approvals will be issued for a duration of 36 months for all indications except fatigue associated with chemotherapy and excessive sleepiness associated with Parkinson's disease; approvals for these conditions will be for a duration of 12 months.

## References

- Provigil [package insert]. Frazer, PA; Cephalon, Inc. 2015 Jan.
- Nuvigil [package insert]. Frazer (PA): Cephalon Inc; 2013 Jun.
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Last reviewed/updated:8/4/15





**Qudexy™ XR (topiramate extended release)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Qudexy™ XR (topiramate ER)**

- **Quantity Limit**
  - 25 mg strength: 90 capsules/30 days if approved
  - 50 mg & 100 mg strengths: 30 capsules/30 days if approved
  - 150 mg & 200 mg strengths: 60 capsules/30 days if approved

**How do I obtain a prior authorization for Qudexy™ XR or Trokendi XR™?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Epilepsy (seizures)

**Approval criteria**

- Patient is a new NHP member and has already been stabilized on Qudexy™ XR for an approvable diagnosis
- OR**
- The diagnosis is epilepsy and the member has had previous medication trials of 2 anticonvulsants, one of which was generic regular-release topiramate (capsules or tablets).

Approvals will be for a duration of 3 years (36 months).

**References**

- French JA, Kanner AM, Bautista J et al. Efficacy and tolerability of the new antiepileptic drugs I: treatment of new onset epilepsy: report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2004 Apr 27;62(8):1252 -60.
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Last reviewed/approved: 11/3/14



**Ranexa<sup>®</sup> (ranolazine) Prior  
Authorization criteria Drug  
Protocol Management**

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**Ranexa<sup>®</sup> (ranolazine)**

- **Quantity Limit**
  - **500 mg strength: 120 tablets/30 days if approved**
  - **1000 mg strength: 60 tablets/30 days if approved**

**How do I obtain a prior authorization for Ranexa<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Chronic angina

**Approval Criteria**

- Patient has a diagnosis of chronic angina **AND**
  - The request is from a cardiologist
- OR**
- Patient has a diagnosis of chronic angina **AND**
  - Patient has had a documented side effect, allergy or inadequate response to at least one drug\* from any two different drug categories including: beta blockers, maintenance nitrates, or calcium channel blockers\*\* **AND**
  - Patient does not have any contraindications to the use of Ranexa<sup>®</sup>, including a history of QT-prolongation or clinically significant liver cirrhosis **AND**
  - The prescriber has been made aware that the patient should not be is not concurrently receiving any of the following medications that may interact with Ranexa<sup>®</sup>:
    - Drugs that may prolong the QT interval (amiodarone, erythromycin, quinidine, sotalol, dofetilide, thioridazine, ziprasidone, etc.)
    - Strong CYP450 3A4 Inhibitors (e.g., ketoconazole, itraconazole, ritonavir, nelfinavir, indinavir, saquinavir, clarithromycin, nefazodone, etc.)<sup>†</sup>
    - CYP 3A isoenzyme inducers (e.g., rifampin, rifabutin, rifapentin, phenobarbital, phenytoin, carbamazepine, St. John's wort, etc.)

\* At least one drug from **two** different categories below (list not all inclusive):

- Beta blockers: metoprolol XL, atenolol, bisoprolol, metoprolol, acebutolol, propranolol, etc.
- Nitrates: isosorbide dinitrate, isosorbide mononitrate, etc.
- Calcium Channel Blockers: amlodipine, nifedipine, nisoldipine, isradipine, felodipine, nicardipine, diltiazem, verapamil, etc.

\*\* Ranexa may be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and ARB's.

<sup>†</sup> Concomitant use of Ranexa with moderate CYP3A inhibitors such as diltiazem, verapamil, erythromycin, fluconazole, and grapefruit juice or grapefruit-containing products, etc. warrant the need for Ranexa dose reductions. Doses of Ranexa should be limited to 500 mg twice daily in these situations. The dose of simvastatin in patients on any dose of Ranexa should be limited to 20mg daily.



**Tamiflu<sup>®</sup> (oseltamivir) and Relenza<sup>®</sup> (zanamivir)**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

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Prior authorization is required for **all** prescriptions for Tamiflu<sup>®</sup> and Relenza<sup>®</sup> during non-flu season (April 1<sup>st</sup> through October 31<sup>st</sup>). During flu season (November 1<sup>st</sup> through March 31<sup>st</sup>), prior authorization is **only** required for Tamiflu<sup>®</sup> and Relenza<sup>®</sup> **if the prescribed quantity exceeds the quantity limits set forth below.**

- **Tamiflu<sup>®</sup> (oseltamivir)**
  - 45mg & 75mg capsules: 10 capsules/30 days
  - 30mg capsules: 20 capsules/30 days
  - Solution: 3 bottles (180ml)/30 days
- **Relenza<sup>®</sup> (zanamivir):**
  - 20 blisters/30 days

**How do I obtain a prior authorization for Tamiflu<sup>®</sup> or Relenza<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Chemoprophylaxis (prevention) of influenza infection after exposure
- Treatment of influenza infection

**Approval Criteria**

**Coverage criteria October 1st-April 30th:**

- The diagnosis is chemoprophylaxis (prevention) of influenza infection after exposure  
**AND**
- The patient has one or more of the following risk factors:
  - Age of  $\geq 50$  years
  - Age between 6 and 59 months
  - Healthcare worker
  - Chronic cardiovascular or pulmonary disease (e.g., including asthma, but not hypertension)
  - Chronic metabolic or endocrine disease (e.g., diabetes, etc.)
  - Morbid obesity (BMI of  $\geq 40$ )
  - Renal failure or hepatic disorder
  - Hematological disorder or a hemoglobinopathy (e.g., sickle cell anemia, thalassemia, etc.)
  - Immunosuppression (e.g., immunosuppression secondary to corticosteroid therapy, immunosuppressive therapy, chemotherapy, HIV/AIDS, etc.)
  - Cancer
  - Current pregnancy or planned pregnancy during flu season
  - American Indian, Alaska native, or resident of a nursing home/long-term care facility/chronic care facility
  - Unvaccinated infant between 12 and 24 months of age
  - Child or adolescent (ages 6 months to 18 years) who is receiving long-term aspirin therapy
  - Any neurological condition that may compromise the handling of respiratory secretions or increase the risk for aspiration (e.g., cognitive dysfunction, spinal cord injuries, seizure & neuromuscular disorders, etc.)

**AND**

- The patient is part of at least one of the following high-risk situations:
  - Absence of vaccination for the current flu season
  - Insufficient time to develop immunity between vaccination and likely exposure
  - Presence of an active outbreak of influenza among institutionalized residents
  - Circulating influenza viruses strains are different than the strains used to develop the vaccine

**AND**

- The patients is  $\geq 1$  year of age (for Tamiflu<sup>®</sup>) or  $\geq 5$  years of age (for Relenza<sup>®</sup>)

**Coverage criteria May 1<sup>st</sup>-September 30<sup>th</sup>:**

- The diagnosis is treatment of influenza

**AND**

- Treatment will begin within 48 hours of the onset of symptoms

**AND**

- The patient is  $\geq 2$  weeks of age (for Tamiflu<sup>®</sup>) or  $\geq 7$  years (for Relenza<sup>®</sup>)

**OR**

- The diagnosis is chemoprophylaxis (prevention) of influenza infection after exposure

**AND**

- The patient has at least one of the following risk factors:
  - Age of  $\geq 50$  years
  - Age between 6 and 59 months
  - Healthcare worker
  - Chronic cardiovascular or pulmonary disease (e.g., including asthma, but not hypertension)
  - Chronic metabolic or endocrine disease (e.g., diabetes, etc.)
  - Morbid obesity (BMI of  $\geq 40$ )
  - Renal failure or hepatic disorder
  - Hematological disorder or a hemoglobinopathy (e.g., sickle cell anemia, thalassemia, etc.)
  - Immunosuppression (e.g., immunosuppression secondary to corticosteroid therapy, immunosuppressive therapy, chemotherapy, HIV/AIDS, etc.)
  - Cancer
  - Current pregnancy or planned pregnancy during flu season
  - American Indian, Alaska native, or resident of a nursing home/long-term care facility/chronic care facility
  - Unvaccinated infant between 12 and 24 months of age
  - Child or adolescent (ages 6 months to 18 years) who is receiving long-term aspirin therapy
  - Any neurological condition that may compromise the handling of respiratory secretions or increase the risk for aspiration (e.g., cognitive dysfunction, spinal cord injuries, seizure & neuromuscular disorders, etc.)

**AND**

- The patient is part of at least one of the following high-risk situations:
  - Absence of vaccination for the current flu season
  - Insufficient time to develop immunity between vaccination and likely exposure
  - Presence of an active outbreak of influenza among institutionalized residents
  - Circulating influenza viruses strains are different than the strains used to develop the vaccine

**AND**

- The patients is  $\geq 1$  year of age (for Tamiflu<sup>®</sup>) or  $\geq 5$  years of age (for Relenza<sup>®</sup>)

### **Additional Information**

- If the patient is a nursing home resident OR has underlying airway disease (e.g., asthma or COPD), Relenza<sup>®</sup> treatment is not recommended.
- In the event of an influenza outbreak, all requests will be evaluated on a case-by-case basis in accordance to recommendations from the Department of Public Health and/or the Centers for Disease Control.

### **References**

- Tamiflu<sup>®</sup> [package insert]. South San Francisco (CA): Genentech, Inc.; 2014 May.
- Relenza<sup>®</sup> [package insert]. Research Triangle Park (NC): GlaxoSmithKline; 2013 Oct.
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**Relistor® (methylnaltrexone)  
Prior Authorization Criteria  
Drug Protocol Management**

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**How do I obtain a prior authorization for Relistor®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Opioid-induced constipation (OIC)

**Approval Criteria**

- Patient has a diagnosis of opioid-induced constipation (OIC) **AND**
- Patient has experienced an inadequate response or intolerance to treatment with at least two (2) different laxative agents (e.g., milk of magnesia, lactulose, polyethylene glycol [PEG], psyllium, senna, bisacodyl, etc.) **AND**
- Patient has experienced an inadequate response or intolerance to treatment with Amitiza® (lubiprostone)

Approvals may be issued for up to 12 months (1 year).

**References**

- Relistor® [package insert]. Raleigh (NC); Salix Pharmaceutical, Inc.: 2014 Sep.
- Thomas J, Karver S, Cooney GA et al. Methylnaltrexone for opioid-induced constipation in advanced disease. *N Engl J Med*. 2008;358:2332-2343.
- Michna E, Blonsky ER, Schulman S, Tzanis E, Manley A, Zhang H, et al. Subcutaneous methylnaltrexone for treatment of opioid-induced constipation in patients with chronic, nonmalignant pain: a randomized controlled study. *Journal of Pain*. 2011;12(5):554-62.
- Anissian L, Schwartz HW, Vincent K, Vincent HK, Carpentino J, Stambler N, et al. Subcutaneous methylnaltrexone for treatment of acute opioid-induced constipation: phase 2 study in rehabilitation after orthopedic surgery. *Journal of hospital Medicine*. 2012;7(2):67-72.
- Rodrigues A, Wong C, Mattiussi A, Alexander S, Lau E, Dupuis LL. Methylnaltrexone for opioid-induced constipation in pediatric oncology patients. *Pediatric Blood & Cancer*. 2013;60(10):1667-70.
- Ford AC, Brenner DM, Schoenfeld PS. Efficacy of Pharmacological therapies for the treatment of opioid-induced constipation: systematic review and meta-analysis. *American Journal of Gastroenterology*. 2013;108(10):1566-74.

Last reviewed/updated: 4/6/15



**Remicade® (infliximab)  
Prior Authorization criteria  
Drug Protocol Management**

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**Remicade® (infliximab) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Remicade®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Rheumatoid arthritis (RA)
- Psoriatic arthritis
- Moderate to severe chronic plaque psoriasis
- Ankylosing spondylitis
- Crohn's disease
- Ulcerative colitis

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Remicade® for an approvable indication

**OR**

- Patient has a diagnosis of rheumatoid arthritis (RA)\*, ankylosing spondylitis, or psoriatic arthritis **AND**
- Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD\*\*, if methotrexate is contraindicated) \*†

**OR**

- Patient has a diagnosis of Crohn's disease or ulcerative colitis **AND**
- Patient has experienced an inadequate response or intolerance to one or more conventional immunomodulator therapies‡

**OR**

- Patient has a diagnosis of moderate to severe chronic plaque psoriasis affecting  $\geq 10\%$  body surface area **AND**
- Patient has experienced an inadequate response or intolerance to at least **one (1)** agent from at least **two (2)** of the following **three (3)** categories:
  - **Topical agents:** emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene
  - **Systemic agents:** methotrexate, sulfasalazine, cyclosporine, tacrolimus, acitretin, mycophenolate mofetil, azathioprine, hydroxyurea, etc.
  - **Phototherapy:** ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB), etc.

\* Infliximab should be used in combination with MTX for the treatment of RA, unless contraindicated or not tolerated

\*\* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

- \*† Methotrexate/DMARD trial requirement may be overridden for patients with documented axial disease in ankylosing spondylitis or psoriatic arthritis whose condition is not adequately controlled with NSAIDs AND for RA patients with documented high disease activity (advanced disease) with features of a poor prognosis (i.e., functional limitations, extra-articular disease, positive rheumatoid factor, or anti-cyclic citrullinated peptide antibodies, & bony erosions by radiograph)
- ‡ Conventional immunomodulator therapies include methotrexate, cyclosporine, azathioprine, tacrolimus, and 6-mercaptopurine

Initial approvals may be issued for up to 6 months for all indications except plaque psoriasis; initial approvals for plaque psoriasis may be issued for up to 3 months.

## Reauthorization Criteria

### All indications except plaque psoriasis

- Improvement per physician and member assessment of overall disease activity/severity

### Plaque psoriasis

- Disease that is less than clear or responding to treatment per physician assessment

Reauthorizations may be granted for up to 1 year for all indications except plaque psoriasis; reauthorizations for plaque psoriasis may be issued for up to 6 months.

## References

- Abramowicz M (ed.). Treatment guidelines. The Medical Letter 2003; 5: 25-32.
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- Remicade® [package insert]. Horsham (PA): Janssen Biotech Inc., 2015 Jan.
- Lichtenstein GR, Hanauer SB, Sandborn WJ, and The Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's Disease in Adults. Am J Gastroenterol. 2009;104:465-83.
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- Saag KG, Teng GG, Patkar NM, Anuntiyo J, Finney C, Curtis JR, et al. American College of Rheumatology 2008: Recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis & Rheumatism (Arthritis Care & Research). 2008;59(6):762-784.
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- [Singh JA](#), [Furst DE](#), [Bharat A](#), [Curtis JR](#), [Kavanaugh AF](#), [Kremer JM](#), et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. [Arthritis Care Res \(Hoboken\)](#). 2012 May;64(5):625-39.
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Last reviewed/updated: 4/6/15





**Restasis® (cyclosporine ophthalmic emulsion)  
Prior Authorization criteria  
Drug Protocol Management**

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**Restasis® (cyclosporine ophthalmic emulsion)**

- **Quantity Limit: 60 vials per month**

**How do I obtain a prior authorization for Restasis®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnoses**

- keratoconjunctivitis sicca (KCS) [dry eye syndrome]
- Sjögren's syndrome
- Being treated for Ocular Graft vs. Host Disease, or Corneal Transplant rejection.

**Approval Criteria**

- The prescribing physician is an ophthalmologist, optometrist or rheumatologist, or the request is recommended by an ophthalmologist, optometrist or rheumatologist **AND**
- Patient has an approvable diagnosis for use of Restasis® **AND**
- Patient has had a documented intolerance, contraindication, or inadequate response to an alternative dry eye agent (e.g., artificial tears) or the patient's need for an alternative agent has increased over time

Approvals will be for a duration of 3 years (36 months).

**References**

- Restasis® [package insert]. Irvine (CA): Allergan, Inc.; 2013 Jun.
- Sall K, et al. Two multicenter, randomized studies of the efficacy and safety of cyclosporine ophthalmic emulsion in moderate to severe dry eye disease. *Ophthalmology* 2000; 107: 631-639.
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- Hoehn ME, Kelly SR, Wilson MW, Walton RC. Cyclosporine 0.05% ophthalmic emulsion for the treatment of radiation-associated dry eye in children. *Pediatric Blood & Cancer*. 2013;60(7):E35-7.
- Chung YW, Oh TH, Chung SK. The effect of topical cyclosporine 0.05% on dry eye after cataract surgery. *Korean Journal of Ophthalmology*. 2013;27(3):167-71.



**Adcirca® (tadalafil) tablets, Revatio® (sildenafil) oral suspension, and  
sildenafil (Revatio®) tablets  
Prior Authorization Criteria  
Drug Protocol Management**

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**sildenafil (Revatio®) 20 mg tablets & Revatio® (sildenafil) oral suspension 10mg/mL:**

**Approval Criteria:**

Requests for sildenafil (Revatio®) will be approved for members who meet the following criteria:

1. The diagnosis/indication is pulmonary hypertension **AND**
2. The quantity limit of #90 tablets/30 days or 2 bottles/30 days (224mL/30 days) has not been exceeded **AND**
3. The member is not using a guanylate cyclase inhibitor (e.g., riociguat [Adempas®]), and is also not using nitrates, either regularly or intermittently

**FDA Approved Indications/dose:**

Sildenafil (Revatio®) is indicated for pulmonary arterial hypertension (WHO group I) to improve exercise ability and delay clinical worsening. The delay in clinical worsening was demonstrated when sildenafil was added to background epoprostenol therapy. Effectiveness studies were short-term (12-16 weeks) & were predominantly in patients with NYHA class II-III symptoms and idiopathic etiology (71%) or associated with connective tissue disease (25%). The recommended dose is 20mg TID.

Note: Revatio® injection is a “packaging exception” and is reviewed on a case-by-case basis.

**Adcirca® (tadalafil) 20mg tablets:**

**Approval Criteria:**

Requests for tadalafil (Adcirca®) will be approved for members who meet the following criteria:

1. The diagnosis/indication is pulmonary hypertension **AND**
2. The quantity limit of #60 tablets/30 days has not been exceeded **AND**
3. The member is not using a guanylate cyclase inhibitor (e.g., riociguat [Adempas®]), and is also not using nitrates, either regularly or intermittently.

**FDA Approved Indications/dose:**

Adcirca® is indicated for the treatment of pulmonary arterial hypertension (WHO Group I) to improve exercise ability. Effectiveness studies were short-term (12-16 weeks) & were predominantly in patients with NYHA class II-III symptoms and etiologies of idiopathic or heritable PAH (61%), or PAH associated with connective tissue diseases (23%). The recommended dose is 40mg daily (2x20mg tablets). Dividing the dose over the course of the day is not recommended. Dose adjustments with renal and hepatic dysfunction as well as with concomitant ritonavir therapy are required.

## **Non-FDA Approved Potential Uses:**

Raynaud's Disease Criteria:

- Trials of:
  - slow-release or long-acting preparations of the dihydropyridine calcium channel blockers (CCB), [nifedipine](#) (30 to 180 mg/day) or [amlodipine](#) (5 to 20 mg/day) and
  - Other alternative therapies include topical nitrates or prazosin

## **References:**

1. Revatio® [package insert], New York, NY: Pfizer, Inc., 2015 Apr.
2. Adcirca® [package insert]. Indianapolis, IN: Eli Lilly & Company, 2015 Apr.
3. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension: a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association: developed in collaboration with the American College of Chest Physicians, American Thoracic Society, Inc., and the Pulmonary Hypertension Association. *Circulation*. 2009 Apr 28;119(16):2250-94.
4. McGoon M, et al. Screening, Early Detection, and Diagnosis of Pulmonary Arterial Hypertension: ACCP Evidence-Based Clinical Practice Guidelines. *Chest*. 2004;126:14S-34S.
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6. Up-To-Date: **Treatment of the Raynaud phenomenon resistant to initial therapy**, Fredrick M Wigley, MD, John S Axford, DSc, MD, FRCP, FRCPC, Monica Ramirez Curtis, MD, MPH Viewed 6/22/16. **Last updated 5/25/16.**



**Savella® (milnacipran HCL)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Savella® (milnacipran HCL)**

- **Quantity Limit**
  - Savella® tablets: 60 tablets/30 days
  - Savella® titration pack: 1 pack (55 tablets) per lifetime

**How do I obtain a prior authorization for Savella®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Fibromyalgia

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Savella® for the approvable indication **OR**
- Patient has a diagnosis of fibromyalgia **AND**
- Patient has had a trial and failure with an SNRI product (e.g. venlafaxine, duloxetine, desvenlafaxine, etc.) **AND**
- Patient has had trials and failures with medications from **two** of the following drug classes/categories:
  - Tricyclic antidepressants (e.g. amitriptyline, doxepin, desipramine, imipramine, etc.)
  - SSRI's (e.g. citalopram, fluoxetine, paroxetine, sertraline, etc.)
  - Cyclobenzaprine
  - Gabapentin

Approvals will be for a duration of 3 years (36 months).

**References**

- Savella® (milnacipran HCL) [package insert]. St. Louis (MO): Forest Laboratories, Inc. 2013.
- Haavisto M. Milnacipran for Treatment of Fibromyalgia. Accessed 2009 August 31 from [http://chronic-illness-treatments.suite101.com/article.cfm/milnacipran\\_for\\_treatment\\_of\\_fibromyalgia](http://chronic-illness-treatments.suite101.com/article.cfm/milnacipran_for_treatment_of_fibromyalgia).
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Last reviewed/updated: 1/12/15



**NHP Pharmacy Department  
Serotonin Modulator Quantity Limit Program  
Trintellix® (vortioxetine) and Viibryd® (vilazodone)**

**Approval Criteria**

NHP will approve the request to exceed the quantity limit if the following conditions are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limit.  
AND
- There is medical necessity to exceed the quantity limit and documentation has been provided.

Last reviewed/updated: 9/2016



**NHP Pharmacy Department  
ADHD Quantity Limit Program  
Drug Protocol Management**

**Approval Criteria**

NHP will approve the request to exceed quantity limit if dose consolidation is not possible and if supplementation with an immediate release formulation has been tried and failed.

Last reviewed/updated: 9/2016



## **Short-Acting Fentanyl Products Prior Authorization Criteria Drug Protocol Management**

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**Short-Acting Fentanyl Products: fentanyl lozenge (Actiq®), Abstral®, Fentora®, Lazanda®, and Susbys®**

### **How do I obtain a prior authorization for a short-acting fentanyl product?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

### **Approvable Diagnosis**

- Management of breakthrough cancer pain

### **Approval Criteria**

#### Fentanyl lozenge (Actiq®)

- Diagnosis is management of breakthrough cancer pain **AND**
- Prescriber is an oncologist or a practitioner (NP, PA, etc.) specializing in oncology or pain management **AND**
- Prescriber is registered in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation (REMS) Access program **AND**
- Patient is tolerant to opioid therapy\* for their underlying cancer pain **AND**
- Patient is currently receiving a long-acting, around-the-clock, opioid analgesic for continuous pain management **AND**
- Patient has had an inadequate response, intolerance, or treatment failure with at least one (1) preferred, short-acting opioid analgesic for their current breakthrough cancer pain (e.g., hydrocodone, hydromorphone, meperidine, morphine, oxycodone, oxymorphone, etc.)

#### Abstral®, Fentora®, Lazanda®, Subsys®

- Diagnosis is management of breakthrough cancer pain **AND**
- Prescriber is an oncologist or a practitioner (NP, PA, etc.) specializing in oncology or pain management **AND**
- Prescriber is registered in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation (REMS) Access program **AND**
- Patient is tolerant to opioid therapy\* for their underlying cancer pain **AND**
- Patient is currently receiving a long-acting, around-the-clock, opioid analgesic for continuous pain management **AND**
- Patient has had an inadequate response, intolerance, or treatment failure with at least one (1) preferred, short-acting opioid analgesic for their current breakthrough cancer pain (e.g., hydrocodone, hydromorphone, meperidine, morphine, oxycodone, oxymorphone, etc.) **AND**
- Patient has had an inadequate response, intolerance, or treatment failure with fentanyl lozenge (Actiq®) for their current breakthrough cancer pain

\*Opioid tolerance is considered greater than or equal to 60 mg morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg of oxycodone daily, 8 mg oral hydromorphone, 25 mg oral oxymorphone or an equianalgesic dose of another opioid for greater than or equal to 1 week

Approvals may be granted for a duration of up to 6 months.



## References

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Last reviewed/updated: 6/27/16



**Methadone Prior Authorization  
Prior Authorization Criteria  
Drug Protocol Management**

**FDA-APPROVED INDICATIONS**

1. For the treatment of moderate to severe pain not responsive to non-narcotic analgesics.
2. For detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
3. For maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

NOTE: Outpatient maintenance and outpatient detoxification treatment may be provided only by Opioid Treatment Programs (OTPs) certified by the Federal Substance Abuse and Mental Health Services Administration (SAMHSA) and registered by the Drug Enforcement Administration (DEA). This does not preclude the maintenance treatment of a patient with concurrent opioid addiction who is hospitalized for conditions other than opioid addiction and who requires temporary maintenance during the critical period of his/her stay, or of a patient whose enrollment has been verified in a program which has been certified for maintenance treatment with methadone.

**Approval Criteria:**

- Member is not opioid naïve AND
- Member has tried and failed or has documented contraindication to long-acting morphine product AND
- Member has tried and failed or has documented contraindication to transdermal fentanyl product AND
- Member has had an ECG showing normal QTc interval.

**REFERENCES**

8. Dolophine Package Insert, Roxane Laboratories, October 2006, Accessed through FDA.gov June 3, 2016

Implemented:  
Reviewed: P&T Mtg 6/22/16  
Reviewed & Updated:



**Simponi<sup>®</sup> & Simponi<sup>®</sup> Aria (golimumab)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Simponi<sup>®</sup> and Simponi<sup>®</sup> Aria (golimumab) are specialty products; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 1 syringe per 30 days applies to Simponi<sup>®</sup>; for Simponi<sup>®</sup> Aria, quantity limits appropriate for the patient consistent with weight-based dosing will be applied when the prior authorization request is approved.**

**How do I obtain a prior authorization for Simponi<sup>®</sup> or Simponi<sup>®</sup> Aria?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

Simponi<sup>®</sup> Aria:

- Moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate

Simponi<sup>®</sup>:

- Moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate
- Active psoriatic arthritis
- Active ankylosing spondylitis
- Moderately to severely active ulcerative colitis (UC)

**Approval Criteria**

Simponi<sup>®</sup> Aria

- Patient is new to NHP and has been stabilized on Simponi<sup>®</sup> Aria for an approvable indication
- OR**
- Patient is  $\geq 18$  years of age **AND**
  - Patient has a diagnosis of moderately to severely active rheumatoid arthritis **AND**
  - Patient is taking methotrexate or has experienced an inadequate response or intolerance to treatment with methotrexate

Simponi<sup>®</sup>

- Patient is new to NHP and has been stabilized on Simponi<sup>®</sup> for an approvable indication
- OR**
- Patient is  $\geq 18$  years of age **AND**
  - Patient has a diagnosis of moderately to severely active rheumatoid arthritis **AND**
  - Patient is taking methotrexate or has experienced an inadequate response or intolerance to treatment with methotrexate

**OR**

- Patient is  $\geq 18$  years of age **AND**
- Patient has a diagnosis of active psoriatic arthritis or ankylosing spondylitis **AND**
- Patient has experienced an inadequate response or intolerance to at least 1 conventional DMARD<sup>\*\*</sup>

**OR**

- Patient is  $\geq 18$  years of age **AND**
- Patient has a diagnosis of moderately to severely active ulcerative colitis **AND**

- Patient has had a demonstrated dependence on corticosteroids for disease management **OR** has experienced an inadequate response or intolerance to treatment with oral aminosalicylates, azathioprine, or 6-mercaptopurine for:
  - Inducing and maintaining clinical response
  - Improving endoscopic mucosa appearance during induction
  - Inducing clinical remission
  - Achieving and sustaining clinical remission in those responding to induction therapy
- \* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline
- ‡ DMARD trial requirement may be overridden for patients with documented axial disease in ankylosing spondylitis or psoriatic arthritis whose condition is not adequately controlled with NSAIDs

Initial approvals for **both** Simponi<sup>®</sup> and Simponi<sup>®</sup> Aria may be issued for up to 6 months<sup>∞</sup>.

<sup>∞</sup> Simponi<sup>®</sup> approvals for the treatment of ulcerative colitis will have quantity limit overrides applied at the prior authorization level to allow for initial dosing regimens/induction therapy.

### Reauthorization Criteria

- Improvement per physician assessment of overall disease activity

Reauthorizations may be granted for up to 1 year.

### References

- Simponi<sup>®</sup> [package insert]. Horsham (PA): Janssen Biotech, Inc.; 2014 Dec.
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Last reviewed/updated: 4/6/15



**Solaraze<sup>®</sup> (diclofenac sodium) 3% topical gel**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

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**Solaraze<sup>®</sup> (diclofenac sodium) 3% topical gel**

**How do I obtain a prior authorization for Solaraze<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approval Diagnosis and Criteria:**

- Diagnosis of actinic keratosis  
**AND**
- A previous failure of topical fluorouracil (e.g., 5-FU, Efudex<sup>®</sup>, etc.), topical imiquimod (Aldara<sup>®</sup>, Zyclara<sup>®</sup>) AND Picato<sup>®</sup> gel  
**OR**
- The member is pregnant

Medications	First-Line Drugs	Second-Line Drugs
	imiquimod (Aldara <sup>®</sup> , Zyclara <sup>®</sup> ) fluorouracil (Efudex <sup>®</sup> , 5-FU, etc.) Picato <sup>®</sup> gel	Solaraze <sup>®</sup> (diclofenac)



**Stelara<sup>®</sup> (ustekinumab)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Stelara<sup>®</sup> (ustekinumab) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Stelara<sup>®</sup>?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Moderate to severe plaque psoriasis
- Psoriatic arthritis

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Stelara<sup>®</sup> for an approvable indication
- OR**
- Patient is  $\geq 18$  years if age **AND**
  - Patient has a diagnosis of moderate to severe plaque psoriasis affecting  $\geq 10\%$  body surface area **AND**
  - Patient has experienced an inadequate response or intolerance to at least **one (1)** agent from at least **two (2)** of the following **three (3)** categories:
    - **Topical agents:** emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene
    - **Systemic agents:** methotrexate, sulfasalazine, cyclosporine, tacrolimus, acitretin, mycophenolate mofetil, azathioprine, hydroxyurea, etc.
    - **Phototherapy:** ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB), etc.
- OR**
- Patient is  $\geq 18$  years if age **AND**
  - Patient has a diagnosis of psoriatic arthritis **AND**
  - Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD\*, if methotrexate is contraindicated) \*†

\* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

\*† Methotrexate/DMARD trial requirement may be overridden for patients with psoriatic arthritis whose condition is not adequately controlled with NSAIDs

Initial approvals may be issued for up to 3 months for plaque psoriasis and for up to 6 months for psoriatic arthritis. Quantity limits will be applied dependent upon individual patient needs and diagnosis.

**Reauthorization Criteria**

Plaque psoriasis

- Disease that is less than clear or responding to treatment per physician assessment

Psoriatic arthritis

- Improvement per physician and member assessment of overall disease activity/severity

Reauthorizations may be granted for up to 6 months for plaque psoriasis and 12 months for psoriatic arthritis.

## References

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Last reviewed/updated:4/6/15



**buprenorphine (Subutex®)  
Prior Authorization criteria  
Drug Protocol Management**

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**How do I obtain a prior authorization for buprenorphine?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Coverage for buprenorphine will be granted given the following conditions:**

- Opioid Dependence  
AND
- Allergy to Naloxone  
OR
- Pregnancy

Initial approval will be for 6 months or until end of pregnancy, if applicable.

**Reauthorization criteria:**

The following clinical information will be required for reauthorization:

1. Documentation of effectiveness and treatment plan.
2. Buprenorphine therapy will be reauthorized for 6 months.

**Quantity limit of 90 tablets / 30 days if approved**





**Symlin<sup>®</sup> (pramlintide) Prior  
Authorization Criteria Drug  
Protocol Management**

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**How do I obtain a prior authorization for Symlin<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**FDA-APPROVED INDICATIONS**

Symlin/SymlinPen is indicated as an adjunctive treatment in patients with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

**COVERAGE CRITERIA**

Symlin/SymlinPen (pramlintide acetate) will be covered with prior authorization when the following criteria are met:

- The patient has been receiving Symlin for at least 3 months.  
AND
  - The patient has demonstrated an expected reduction in HbA1c since starting the therapy.
- OR**
- The patient has not been receiving Symlin for at least 3 months.  
AND
  - The patient does not having any of the following:
    - recurrent severe hypoglycemia that required assistance during the past 6 months
    - gastroparesis
    - patient requires drug therapy to stimulate gastrointestinal motility
    - hypoglycemia unawareness (e.g., inability to detect and act upon the signs or symptoms of hypoglycemia)
    - an HbA1c level greater than 9 percent
  - AND
  - The patient is currently receiving optimal mealtime insulin therapy.  
AND
  - The patient has experienced an inadequate treatment response to insulin  
AND
  - The patient has a diagnosis of type 1 or type 2 diabetes mellitus

## **RATIONALE**

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines.

Symlin/SymlinPen is indicated as an adjunctive treatment in patients with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

Clinical guidelines for the management of hyperglycemia in type 2 diabetes issued by the American Diabetes Association (ADA) indicate that an HbA1c of greater than 7% serves as a call to action. Lowering A1c to approximately 7% or less has been shown to reduce microvascular complications of diabetes, and, if implemented soon after the diagnosis of diabetes, it is associated with long-term reduction in macrovascular disease. Therefore, a reasonable A1c goal for many nonpregnant adults is <7%. While the American Diabetes Association Standards of Medical Care in Diabetes recommends lowering the A1C to less than 7% in most patients, some patients may benefit from less stringent A1c goals. A less stringent A1c goal (such as <8%) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, or long-standing diabetes in whom the general goal is difficult to attain despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin. However, providers might reasonably suggest more stringent A1c goals (such as <6.5%) for selected individual patients if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients may include those with short duration of diabetes, type 2 diabetes treated with lifestyle or metformin only, long life expectancy, or no significant cardiovascular disease.<sup>5</sup>

The American Diabetes Association reports that because A1c is thought to reflect average glycemia over several months, and has strong predictive value for diabetes complications, A1c testing should be performed routinely in all patients with diabetes, at initial assessment and as part of continuing care. Measurement approximately every 3 months determines whether the patient's glycemic targets have been reached and maintained.<sup>5</sup> Therefore, continued use of Symlin/SymlinPen will be approved for patients who have demonstrated an expected reduction in HbA1c since starting Symlin therapy for at least three months.

## **REFERENCES**

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Respiratory syncytial virus (RSV)  
Season 2016–2017  
(November to March)



## Synagis—Prior Authorization Guidelines

### Overview

Synagis dispensing is available from NHP's preferred specialty pharmacy provider, CVS/caremark, or other contracted specialty pharmacy. NHP will be covering the cost of the injection as well as the administration of Synagis throughout the Respiratory Syncytial Virus (RSV) infection season (November through March) only if obtained from a contracted specialty pharmacy. Synagis and all supplies necessary for the administration will be shipped out and delivered to your office within 24 to 48 hours after ordering. NHP can be billed for administration of the drug.

### Requesting Authorization: How do I get it?

1. Complete the Synagis Enrollment Form and fax directly to CVS/caremark at (866) 249-6155. If you have questions, call (866) 814-5506.
2. If your patient meets the below criteria, Synagis will be delivered to your office within 24 to 48 hours after ordering.

### Approval Process

For patients who meet criteria, Synagis will be approved for the entire RSV season for a maximum of five monthly doses during RSV season, beginning November 1. Synagis coverage is not recommended beyond March 15 unless there is evidence of significant ongoing community circulation of RSV. Infants born during the RSV season will need fewer than five monthly doses.

### Prior Authorization form

The Synagis prior authorization form can be found at:

<https://www.nhp.org/provider/pharmacy/Pages/Prior-Authorization.aspx>

Approval of Synagis will be granted if the patient meets any of the following criteria:

Group	Younger than 12 months of age at start of RSV season	Second year of life
Preterm infants without CLD or CHD	Indicated if born before 29 weeks, 0 days. Infants born during the RSV season will need fewer than five monthly doses.	Not indicated.
Preterm infants with CLD	Indicated if born before 32 weeks, 0 days and require >21% oxygen for at least the first 28 days after birth.	Indicated if born before 32 weeks, 0 days (must have satisfied first season CLD criteria) and continue to require medical support (chronic systemic corticosteroid, diuretic, bronchodilator or supplemental oxygen therapy) within six months of start of RSV season.

(cont.)

Group	Younger than 12 months of age at start of RSV season	Second year of life
Preterm infants with CHD*	Indicated in hemodynamically significant CHD, including infants with acyanotic heart disease who are receiving medication to control CHF and will require cardiac surgical procedures and infants with moderate to severe PAH.	Not indicated.
Infants who receive cardiac transplant during RSV season	Indicated.	Indicated.
Infants with anatomic pulmonary abnormalities or neuromuscular disorders that impair the ability to clear respiratory secretions from the upper airway because of ineffective cough	Indicated.	Not indicated.
Infants who are profoundly immunocompromised during RSV season	Indicated.	Indicated.
Infants with CF	CF + CLD and/or nutritional compromise.	CF + Severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) OR CF + weight for length less than 10 <sup>th</sup> percentile.

\*The following groups of infants with CHD are not at increased risk of RSV infection and generally should not receive immunoprophylaxis:

- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children in the second year of life

Other recommendations from the AAP policy statement:

- Synagis should be discontinued for the rest of the RSV season following RSV-associated hospitalization
- Synagis should not be used during hospitalization for RSV
- Patients should not receive more than 5 monthly doses of Synagis per RSV season; qualifying infants born during the RSV season may require fewer than five doses
- Patients with Down's Syndrome should be treated the same way as those without the condition
- Synagis is not recommended for primary asthma prevention or to reduce subsequent episodes of wheezing

## References

1. American Academy of Pediatrics Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Policy Statement. Pediatrics 2014;134:415-420.
2. American Academy of Pediatrics Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Technical Report. Pediatrics 2014;134:e620-e638.



**Tecfidera® (dimethyl fumarate) Prior Authorization Criteria Drug Protocol Management**

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**Tecfidera® (dimethyl fumarate) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 2 capsules per day applies; Starter Kit is limited to a one-time only fill.**

**How do I obtain a prior authorization for Tecfidera®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable**

**Diagnosis**

- Relapsing forms of multiple sclerosis (MS)

**Approval Criteria**

- The member is new to NHP and has been stabilized on Tecfidera® for the approvable indication

**OR**

- The patient has a diagnosis of a relapsing form of MS **AND**
- The prescribing physician is a neurologist or MS specialist

Initial authorizations may be approved for up to 12 months.

Note: Medical necessity rationale for oral dimethyl fumarate due to needle-phobia as well as all other indications beyond the FDA-approved indication will be evaluated on a case-by case basis.

**Reauthorization criteria**

- Improvement per physician assessment of overall disease activity, including a reduction in clinical exacerbations and/or prevention of worsening of physical disability
- Reauthorizations may be granted for a duration of up to 12 months

**References**

- Tecfidera® [package insert]. Cambridge (MA): Biogen Idec, Inc.; 2013 Mar.
- National Multiple Sclerosis Society [homepage on the internet]. National Multiple Sclerosis Society; 2014 [cited 2014 Aug 15]. Available at: <http://www.nationalmssociety.org/>.
- Fox RJ, Miller DH, Phillips T, Hutchinson M, Havrdova E, Kita M et al. Placebo-controlled phase 3 study of oral BG-12 or glatiramer in multiple sclerosis. *N Engl J Med*. 2012;367:1087-97.
- Gold R, Kappos L, Arnold DL, Bar-Or A, Giovannoni G, Selmaj K et al. Placebo-controlled phase 3 study of oral BG-12 for relapsing multiple sclerosis. *N Engl J Med*. 2012(a);367:1098-107.
- Goodin DS, Frohman EM, Garmany GP. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002;58(2):169-78.



**Trokendi XR™ (topiramate extended release)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Trokendi XR™ (topiramate ER)**

- **Quantity Limit**
  - **25 mg strength: 90 capsules/30 days if approved**
  - **50 mg & 100 mg strengths: 30 capsules/30 days if approved**
  - **200 mg strength: 60 capsules/30 days if approved**

**How do I obtain a prior authorization for Trokendi XR™?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Epilepsy (seizures)

**Approval criteria**

- Patient is a new NHP member and has already been stabilized on Trokendi XR™ for an approvable diagnosis
- OR**
- The diagnosis is epilepsy and the member has had previous medication trials of 2 anticonvulsants, one of which was generic regular-release topiramate (capsules or tablets).

Approvals will be for a duration of 3 years (36 months).

**References**

- French JA, Kanner AM, Bautista J et al. Efficacy and tolerability of the new antiepileptic drugs I: treatment of new onset epilepsy: report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2004 Apr 27;62(8):1252 -60.
- French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs II: treatment of refractory epilepsy: report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2004 Apr 27;62(8):1261 -73.
- Glauser T, Ben-Menachem E, Bourgeois B, et al. Updated ILAE evidence review of antiepileptic drug efficacy and effectiveness as initial monotherapy for epileptic seizures and syndromes. *Epilepsia*. 2013 Mar; 54(3):551-563.
- Micromedex® Healthcare Series [topiramate]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically. Available from: <http://www.thomsonhc.com/>. Accessed September 8, 2013.
- TROKENDI XR prescribing information. Supernus Pharmaceuticals, Inc. Rockville, MD. August 2013.
- QUDEXY XR prescribing information. Upsher-Smith Pharmaceuticals, Inc. Maple Grove, MN. March 2014.

Last reviewed/updated: 11/3/14



**Nonformulary Meter  
Prior Authorization Criteria  
Drug Protocol Management**

**Approval Criteria:**

- The patient is on an insulin pump that requires the corresponding meter.

Last reviewed/updated: 5/17/16

**Nonformulary Diabetic Test Strips  
Prior Authorization Criteria  
Drug Protocol Management**

**Approval Criteria:**

- The patient is on an insulin pump that requires nonformulary test strips for the corresponding meter.

**AND**

- The requested quantity is for no more than 8 test strips per day.  
**OR**
- The patient has a medical need for testing more frequently than 8 times per day.

Last reviewed/updated: 5/17/16

**Diabetic Test Strips Post Limit  
Prior Authorization Criteria  
Drug Protocol Management**

**Approval Criteria:**

- The patient has been diagnosed with gestational diabetes or a short-term condition.  
**OR**
- The patient is on an insulin pump.  
**OR**
- The patient has documented poor or fluctuating blood sugar control.

Last reviewed/updated: 5/17/16





**Topical Immunomodulators Post Limit  
Prior Authorization Criteria  
Drug Protocol Management**

**Approval Criteria:**

- The requested medication will not be applied to the face, eyelids, groin, or diaper area.  
**AND**
- The requested medication will be applied to the arm(s), leg(s), chest, back or other areas.
- The approved quantity is dependent upon the patient's affected body surface area percentage.





**Tysabri® (natalizumab)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Tysabri® (natalizumab) is a limited distribution specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Tysabri®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnoses**

- Relapsing forms of multiple sclerosis
- Moderately to severely active Crohn's disease

**Approval Criteria**

- Patient has a documented diagnosis of a relapsing form of multiple sclerosis **AND**
- Documentation is provided that the care plan is to use Tysabri® as monotherapy only (i.e., it will not be used in combination with immunosuppressants or inhibitors of TNF- $\alpha$ ), with confirmation that the appropriate wash-out periods of previously administered therapies have occurred **AND**
- Documentation of participation in the TOUCH program is provided **AND**
- Patient does not have any concomitant conditions (e.g., HIV, leukemia, organ transplant, etc.) or medication therapies (e.g. chemotherapy agents, immunosuppressants, immunomodulators, etc.) that may suppress the immune system and increase the risk of PML development **AND**
- The requested dosing regimen is 300 mg administered intravenously every 4 weeks

**OR**

- Patient has a documented diagnosis of moderately to severely active Crohn's disease and has had an inadequate response to, or is unable to tolerate, conventional DMARD therapies **AND**
- Patient has experienced a documented treatment failure with **both** Humira® (adalimumab) **and** Remicade® (infliximab) **AND**
- Documentation is provided that the care plan is to use Tysabri® as monotherapy only (initial steroid use is acceptable, with plans to taper in order to achieve Tysabri® as monotherapy), with confirmation that the appropriate wash-out periods of previously administered therapies have occurred **AND**
- Documentation of participation in the TOUCH program is provided **AND**
- Patient does not have any concomitant conditions (e.g., HIV, leukemia, organ transplant, etc.) or medication therapies (e.g., chemotherapy agents, immunosuppressants, immunomodulators) that may suppress the immune system and increase the risk of PML development **AND**
- The requested dosing regimen is 300 mg administered intravenously every 4 weeks

Initial approvals for multiple sclerosis may be issued for up to 6 months; initial approvals for Crohn's diseases may be issued for up to 3 months.

## **Reauthorization Criteria**

### **Multiple Sclerosis**

- Documentation of effectiveness, defined as one of the following:
  - A decrease in the number or relapses
  - A slowing change in disability scores (EDSS)
- Prescriber certification that the patient is routinely being monitored for the development of signs or symptoms suggestive of PML
- Continued compliance with the TOUCH program

### **Crohn's Disease**

- Improvement per physician assessment/evaluation of overall disease activity
- Prescriber certification that the patient is routinely being monitored for the development of signs or symptoms suggestive of PML
- Continued compliance with the TOUCH program

Reauthorizations may be granted for up to 6 months.

## **References**

- Tysabri® [package insert]. San Francisco, CA: Elan Pharmaceuticals, Inc.; 2013 Dec.
- Boster A, Edan G, Frohman E, Javed A, Stuve O, Tselis A, et al. Intense immunosuppression in patients with rapidly worsening multiple sclerosis: treatment guidelines for the clinician. *Lancet Neurology*. 7(2):173-83, 2008 Feb.
- Sandborn WJ, Colombel JF, Enns R, Feagan BG, Hanauer SB, Lawrance JC. Natalizumab induction and maintenance therapy for Crohn's disease. *N Engl J Med*. 2005;353:1912-25.
- Lichtenstein GR, Hanauer SB, Sandborn WJ, et al. Management of Crohn's disease in adults. *Am J Gastroenterol*. 2009. Available at: <http://gi.org/clinical-guidelines/>

Last reviewed/updated: 8/3/15



**Uloric<sup>®</sup> (febuxostat) Prior  
Authorization Criteria Drug  
Protocol Management**

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**Uloric<sup>®</sup> (febuxostat)**

- **Quantity Limit: 30 tablets/30 days**

**How do I obtain a prior authorization for Uloric<sup>®</sup>?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnosis**

- Gout

**Approval Criteria**

- Patient has a diagnosis of gout **AND**
- Patient has tried allopurinol and experienced one of the following:
  - An inadequate response or treatment failure with allopurinol at a dose of  $\geq 600$  mg daily (< 600 mg daily if patient has renal dysfunction) **OR**
  - A documented side-effect, allergy or contraindication to allopurinol

Approvals will be for a duration of 3 years (36 months).

**References**

- Uloric<sup>®</sup> [package insert] Deerfield (IL): Takeda Pharmaceuticals America, Inc.; 2013 Mar.

Last reviewed/updated: 1/12/15



## **Calcitriol (Vectical®) Prior Authorization Criteria Drug Protocol Management**

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### **Calcitriol (Vectical®)**

- **Maximum of 200 grams (2 tubes) per week if approved.**

### **How do I obtain a prior authorization for calcitriol (Vectical®)?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

### **Approvable Diagnosis**

- Mild-to-moderate plaque psoriasis.

### **Approval Criteria**

- Patient is a new NHP member and has already been stabilized on calcitriol (Vectical®) ointment for an approvable indication

**OR**

- Patient is  $\geq 18$  years of age **AND**
- Patient has a diagnosis of mild-to-moderate plaque psoriasis **AND**
- Patient has had a documented inadequate response, adverse reaction, or contraindication to the use of two (2) different preferred topical corticosteroid products<sup>†</sup> **AND**
- Patient has demonstrated inadequate response, adverse reaction or contraindication to calcipotriene cream (Dovonex®)

<sup>†</sup> Examples of common topical corticosteroids (not all inclusive) used for the management of plaque psoriasis, based upon affect area, include:

- On the scalp or in the external ear canal, potent corticosteroids (e.g., fluocinonide 0.05%, clobetasol propionate 0.05%, etc.) are frequently indicated
- On the face and intertriginous areas (i.e., locations where two skin areas may touch or rub together), a low potency cream (e.g., hydrocortisone 1%, etc.) is often sufficient  
For thick plaques on extensor surfaces, potent preparations (e.g., betamethasone 0.05%, clobetasol propionate 0.05%, etc.) are often required

Initial authorizations may be approved for up to 6 months.

### **Recertification Criteria**

- Improvement per physician assessment/evaluation of overall disease and the need for continuation of therapy
- Reauthorizations may be granted for a duration of 1 year

### **References**

- Vectical® [package insert]. Fort Worth (TX): Galderma Laboratories LP; 2012 Jul.
- Feldman SR. Treatment of Psoriasis. In: Basow DS (Ed.). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2014. Available from: <http://www.utdol.com/utd/index.do>.
- Mason AR, Mason J, Cork M, et al. Topical treatments for chronic plaque psoriasis. Cochrane Database Syst Rev 2013; 3:CD005028.
- Ortonne JP, Humbert P, Nicolas JF, et al. Intra-individual comparison of the cutaneous safety and efficacy of calcitriol 3 microg g(-1) ointment and calcipotriol 50 microg g(-1) ointment on chronic plaque psoriasis localized in facial, hairline, retroauricular or flexural areas. Br J Dermatol 2003; 148:326.

- Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. American Academy of Dermatology. J Am Acad Dermatol. 2009;60:643-59. Available from: <http://www.aad.org/education/clinical-guidelines>
- Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Micromedex®; 2014]. Available from: <http://www.thomsonhc.com/>.

Last reviewed/updated: 11/10/14



**Viberzi (eluxadoline) Prior Authorization Criteria  
Drug Protocol Management**

**Viberzi (eluxadoline) 75mg and 100mg Tablets: Prior Authorization Criteria**

Viberzi will be approved if all of the following criteria are met:

1. The diagnosis irritable bowel syndrome with diarrhea (IBS-D) **AND**
2. The member tried and failed dietary and lifestyle modifications **AND**
3. The member experienced an allergy or side effect with or has the member had at least a 1-week trial resulting in treatment failure or inadequate response with loperamide.

**References:**

1. Viberzi™ [package insert Actavis Pharma, Inc. Parsippany, NJ, 2016 January
2. **Wald, Arnold : Up-To-Date: Treatment of irritable bowel syndrome in adults. Updated on 8/10/2016.**

Created: 06/27/16 P&T Mtg



**Xartemis™ XR (oxycodone HCl/acetaminophen)  
Benefit Exception Criteria  
Drug Protocol Management**

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**Xartemis™ XR (oxycodone HCl/acetaminophen) is a plan/benefit exclusion. Consideration for coverage of this agent will only be given to patients who have met all of the approval criteria below. If approved, a quantity limit of 60 tablets per 15 days applies.**

**How do I obtain a benefit exception for Xartemis™ XR?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnoses**

- Acute, severe pain

**Approval Criteria**

- Patient has a diagnosis of acute, severe pain **AND**
- Patient has experienced a documented inadequate response with each of the following\* (unless medically contraindicated) used for at least 7 days in duration:
  - tramadol/acetaminophen (Ultracet®)
  - hydrocodone/acetaminophen (Vicodin®, Lortab®, etc.)
  - oxycodone/acetaminophen (Percocet®, Endocet®, Roxicet®, etc.)
  - codeine/acetaminophen (Tylenol® with codeine, etc.)
  - hydrocodone/ibuprofen (Vicoprofen®)

\* Note: the individual components of the listed products administered together will satisfy the trial requirement

A one-time approval may be granted for a duration of 30 days only.

**References**

- American Academy of Orthopaedic Surgeons (AAOS) evidence-based guideline on treatment of osteoarthritis of the knee, 2nd edition. 2013 May 18. Available at: <http://www.aaos.org/Research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.pdf> Accessed: September 18, 2014.
- Attal N, Crucco G, Baron R, et al. EFNS guidelines on the pharmacological treatment of neuropathic pain, 2010 revision. Eur J Neurol. 2010 Sep;17(9):1113-88.
- Boulton AJM, Vinik AI, Arezzo JC, et al. Diabetic Neuropathies (a statement by the American Diabetes Association). Diabetes Care 2005; 28(4):956-62.
- Bril V, England J, Franklin GM, et al. Evidence based guideline: treatment of painful diabetic neuropathy (a report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. Neurology. 2011 Aug;77(6):1758-65.
- Carville SF, Arendt-Neilsen S, Bliddal H, et al. EULAR evidence-based recommendations for the management of fibromyalgia syndrome. Ann Rheum Dis. 2008 Apr;67(4):536-41.
- Chou R, Fanciullo GJ, Fine PG, et al for The American Pain Society—American Academy of Pain medicine Opioids Guidelines Panel. Opioid treatment guidelines: clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain. 2009 Feb;10(2):113-30.
- Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007;147:478-91.
- Crews KR, Gaedigk A, Dunnenberger HM, et al. Clinical Pharmacogenetics Implementation consortium guidelines for cytochrome P450 2D6 genotype and codeine therapy: 2014 update. Clin Pharmacol Ther. 2014;95(4):376-82.
- Dubinsky RM, Kabbani H, El-Chami Z, et al. Practice parameter: treatment of postherpetic neuralgia: an evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2004 Sep;63(6):959-65.
- Food and Drug Administration (FDA). FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm> . Accessed April 29, 2014.

- Formulary Watch. Xartemis XR receives FDA approval: May reduce opioid abuse. March 28, 2014. Available at: <http://formularyjournal.modernmedicine.com/formulary-journal/news/xartemis-xr-receives-fda-approval-may-reduce-opioid-abuse?page=full>. Accessed April 28, 2014.
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- Mallinckrodt Pharmaceuticals. Mallinckrodt plc receives FDA approval for XARTEMIS XR (oxycodone hydrochloride and acetaminophen) extended-release tablets (CII) [press release]. March 12, 2014. Available at: [http://phx.corporate-ir.net/phoenix.zhtml?c=251847&p=irol-newsArticle\\_print&ID=1908261&highlight=](http://phx.corporate-ir.net/phoenix.zhtml?c=251847&p=irol-newsArticle_print&ID=1908261&highlight=). Accessed April 28, 2014.
- Manchikanti L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: part 2—guidance. *Pain Physician.* 2012 Jul;15(3 Suppl):S67-116.
- Medical Letter, Inc. Treatment guidelines from the Medical Letter: Drugs for Pain. 2013;11(128):31-42.
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Last reviewed/updated: 4/6/15





## **Xeljanz® (tofacitinib) Prior Authorization Criteria Drug Protocol Management**

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**Xeljanz® (tofacitinib) is a specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 60 tablets per 30 days applies.**

### **How do I obtain a prior authorization for Xeljanz®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

### **Approvable Diagnosis**

- Moderately to severely active rheumatoid arthritis

### **Approval Criteria**

- Patient is new to NHP and has been stabilized on Xeljanz® for the approvable diagnosis
- OR**
- Patient has a diagnosis of moderately to severely active rheumatoid arthritis **AND**
  - Patient has experienced an inadequate response or intolerance to treatment with methotrexate (or another DMARD\*, if methotrexate is contraindicated)\*\*†

\* Conventional DMARDs include methotrexate, hydroxychloroquine, leflunomide, cyclophosphamide, sulfasalazine, azathioprine, cyclosporine, and minocycline

\*\*† Methotrexate/DMARD trial requirement may be overridden for patients with documented high disease activity (advanced disease) with features of a poor prognosis (i.e., functional limitations, extra-articular disease, positive rheumatoid factor, or anti-cyclic citrullinated peptide antibodies, & bony erosions by radiograph)

Initial approvals may be issued for up to 6 months.

### **Recertification Criteria**

- Documentation from within the previous three months indicating overall disease activity improvement, symptom improvement, and the following laboratory test results:
  - Lymphocyte count  $\geq 500$  cells/mm<sup>3</sup>
  - Absolute neutrophil count (ANC)  $> 500$  cells/mm<sup>3</sup>
  - Hemoglobin level  $\geq 8.0$  g/dL, with no more than a 2 g/dL since initiation of Xeljanz® treatment

Reauthorizations may be granted for up to 12 months.

### **References**

- Arthritis Foundation. Rheumatoid Arthritis. Available at: [http://www.arthritis.org/#\\_ga=1.50767977.1142909394.1422473143](http://www.arthritis.org/#_ga=1.50767977.1142909394.1422473143). Accessed 28 January 2015.
- Burmester GR, Blanco R, Charles-Schoeman C, Wollenhaupt J, Zerbini C, Benda B., et al. Tofacitinib (CP-690,550) in combination with methotrexate in patients with active rheumatoid arthritis with an inadequate response to tumour necrosis factor inhibitors: a randomised phase 3 trial. ORAL Step investigators. Lancet. 2013 (Feb 9);381(9865):451-60.
- Centers for Disease Control and Prevention (CDC). Arthritis-related statistics. Available at: [http://www.cdc.gov/arthritis/data\\_statistics/arthritis\\_related\\_stats.htm#2](http://www.cdc.gov/arthritis/data_statistics/arthritis_related_stats.htm#2). Accessed 28 January 2015..
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- Fleischmann R, Kremer J, Cush J, et al. Placebo-controlled trial of tofacitinib monotherapy in rheumatoid arthritis. NEJM. 2012. 367:6:495-507.

- Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care & Research*. May 2012;64(5):625-639.
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Last reviewed/updated: 4/6/15



**Xenazine® (tetrabenazine)  
Prior Authorization Criteria  
Drug Protocol Management**

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**Xenazine® (tetrabenazine) is a limited distribution specialty product; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark. A quantity limit of 120 tablets per 30 days applies.**

**How do I obtain a prior authorization for Xenazine®?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approvable Diagnosis**

- Chorea associated with Huntington disease

**Approval Criteria**

- Patient is new to NHP and has been stabilized on Xenazine® for the approvable indication

**OR**

- Patient has a diagnosis of chorea associated with Huntington disease **AND**
- Xenazine® is being prescribed by a neurologist

Initial approvals may be issued for up to 12 months.

**Reauthorization Criteria**

- Improvement per physician assessment/evaluation of overall disease activity

Reauthorizations may be granted for up to 36 months.

**References**

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**Xgeva® (denosumab) Prior  
Authorization criteria Drug  
Protocol Management**

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**Xgeva® (denosumab) is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

**How do I obtain a prior authorization for Xgeva?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions.

**Approval diagnosis:**

- Prevention of skeletal-related events in patients with bone metastases from solid tumors

\*\*\_Xgeva is not indicated for the prevention of skeletal-related events in patients with multiple myeloma.

**Approval Criteria:**

- Used for the prevention of skeletal-related events in patients with bone metastases from solid tumors.

All other indications will be evaluated on a case-by case basis.



## Xolair® (omalizumab) Prior Authorization criteria

**Xolair® (omalizumab) is a specialty drug; dispensing is available from NHP's preferred specialty pharmacy provider CVS/caremark.**

### How to I obtain Xolair?

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions

### Criteria for Coverage:

- a. Age  $\geq$  12 years and  $<$  65 years.
- b. Patient must be under the active care of a pulmonologist or allergist and prescription must be written by pulmonologist or allergist.
- c. Patient must not be an active smoker.
- d. Patient must have moderate/severe persistent allergy-related asthma<sup>1</sup>.

**Note:** Not indicated for treatment of acute asthma exacerbations, acute bronchospasms or status asthmaticus.

### Labs for Coverage:

- a. Must submit total IgE level & specific allergy testing results conducted within past 2 years to allergens (RAST or SPT).
- b. IgE levels—must be between 30-1300 IU/mL for children and between 30-700 IU/mL for adults
- c. Patient has a positive skin test or *in vitro* testing (ie, a blood test for allergen-specific IgE antibodies such as the radioallergosorbent test (RAST)) for one or more perennial aeroallergens.
- d. Patient must have pre-bronchodilator FEV1 performed within the past 6 months

### Medications for Coverage:

- a. Patient must be maintained on and adherent to (taking at least 80% of daily doses) **high dose** inhaled steroids for a minimum of 6 weeks such as the following:

	<u>Beclomethasone</u> QVAR®	<u>Budesonide</u> Pulmicort®	<u>Flunisolide</u> AeroBID®	<u>Fluticasone</u> Flovent®	<u>Mometasone</u> Asmanex®	<u>Triamcinolone</u> Azmecort®
Adults	>480 mcg/d	>1200mcg/d	>2000mcg/d	>660mcg/d	>400mcg/d	>1500mcg/d

**plus**

a long-acting bronchodilator (such as Serevent®, Foradil®, or Arcapta® Neohaler®, etc.)

**and/or**

a leukotriene modifier (e.g., Singulair®, Accolate®, or Zyflo®)

**or**

high dose Advair Diskus® ( $\geq$ 500/50 twice daily), or  
 high dose Advair HFA® ( $\geq$  115/21, 2 puffs twice daily), or  
 high dose Symbicort® ( $\geq$  160/4.5, 2 puffs twice daily), or  
 high dose Dulera® ( $\geq$  200/5; 2 puffs twice daily)

**or**

daily systemic steroid therapy

- b. Patient has at least 1 claim in the last 6 months for a bronchodilator to control acute symptoms (such as albuterol, Alupent®, Maxair®, Proventil®, Ventolin®, or Xopenex®, etc).



**Symptomatic:**

Despite adequate adherence to above therapy, patient must be actively symptomatic as evidenced by:

- daily use of bronchodilator therapy, or
- an asthma hospitalization within the past 12 months, or
- > 2 systemic steroid bursts within past 3 months.

**Appropriate Dosing:**

**ADMINISTRATION EVERY 4 WEEKS (Milligrams of omalizumab)**

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	61-70	71-90	91-150
30-100	150	150	150	300
101-200	300	300	300	
201-300	300			

**ADMINISTRATION EVERY 2 WEEKS (Milligrams of omalizumab)**

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	61-70	71-90	91-150
101-200				225
201-300		225	225	300
301-400	225	225	300	X
401-500	300	300	375	X
501-600	300	375	X	X
601-700	375	X	X	X

X = DO NOT DOSE\*

\*dosing that is not recommended by the manufacturer will not be approved

*If patient meets all of the above criteria, authorization for Xolair will be granted for 6 months (initial approval). Xolair should only be administered in a healthcare setting by healthcare providers prepared to manage anaphylaxis that can be life-threatening. Providers must confirm that Xolair will be administered only in a healthcare setting.*

**Recertification:**

Documentation of improvement in FEV1, PEF, PFTs and decreased steroid requirement must be provided for continuation of therapy (12 month approval). Providers must confirm that Xolair will be administered only in a healthcare setting.

**OR**

Documentation of improvement in symptoms or reduced frequency of exacerbations (especially hospital-based) even in the absence of PFTs or steroid requirement improvement (12 month approval). Providers must confirm that Xolair will be administered only in a healthcare setting.



**Xopenex<sup>®</sup> (levalbuterol)**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

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Products Included in the Xopenex <sup>®</sup> Prior Authorization Program
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Levalbuterol (Xopenex <sup>®</sup> ) <u>concentrated</u> nebulizer solution (1.25mg/0.5ml)
Levalbuterol (Xopenex <sup>®</sup> ) nebulizer solution (0.31mg/3mL, 0.63mg/3mL, & 1.25mg/3mL)
Xopenex <sup>®</sup> (levalbuterol) HFA inhalation aerosol (metered dose inhaler)

**How do I obtain a prior authorization for levalbuterol (Xopenex<sup>®</sup>)?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approval Criteria**

- The patient has experienced a documented side-effect or treatment failure with an inhaled albuterol-containing product\*

\*Preferred Agents:

- albuterol nebulizer solution: Duoneb<sup>®</sup>, Accuneb<sup>®</sup>, etc.
- albuterol metered-dose inhaler (MDI) or dry powder inhaler: albuterol, Proventil<sup>®</sup> HFA, Ventolin<sup>®</sup> HFA, Combivent<sup>®</sup>, etc.

Approvals will be for a duration of 3 years (36 months).

**References**

- Xopenex<sup>®</sup> Inhalation aerosol [package insert]. Marlborough (MA): Sunovion Pharmaceuticals Inc.; 2013 Sep.
- Xopenex<sup>®</sup> Inhalation solution [package insert]. Marlborough (MA): Sunovion Pharmaceuticals Inc.; 2014 Mar.
- Xopenex<sup>®</sup> Inhalation solution concentrate [package insert]. Marlborough (MA): Sunovion Pharmaceuticals Inc.; 2014 Mar.
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Last reviewed/updated: 11/10/14



**Zohydro™ ER (hydrocodone bitartrate extended release)  
Benefit Exception Criteria  
Drug Protocol Management**

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**Zohydro™ ER (hydrocodone bitartrate extended release) is a plan/benefit exclusion. Consideration for coverage of this agent will only be given to patients who have met all of the approval criteria below. If approved, a quantity limit of 60 tablets per 30 days applies.**

**How do I obtain a benefit exception for Zohydro™ ER?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approvable Diagnoses**

- Severe pain requiring daily, around-the-clock, long-term opioid treatment

**Approval Criteria**

- Patient is  $\geq 18$  years if age **AND**
- Patient has an underlying diagnosis causing severe pain that requires around-the-clock analgesia with chronic opioid therapy **AND**
- Requested Zohydro™ ER dosing regimen is not for as-needed (PRN) use and does not exceed the daily dose limit of 160 mg **AND**
- Patient does not have a history of alcohol abuse that could place them at increased risk of overdose/fatality **AND**
- Provider offers clinically sound medical rationale for the use of Zohydro™ ER **AND**
- Patient's severe pain has remained uncontrolled despite adequate treatment with non-opiate therapies (acetaminophen, ibuprofen, tramadol, topical remedies, etc.) **AND**
- Patient's severe pain has remained uncontrolled despite adequate treatment with opiate therapies, including all of the following:
  - morphine extended-release tablets or capsules (MS Contin®, Avinza®, Kadian®, etc.)
  - fentanyl transdermal (Duragesic®)
  - oxycodone extended-release tablets (OxyContin®)
  - hydromorphone extended-release tablets (Exalgo® ER)

Approvals will be for a duration of 12 months.

**References**

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- Risk evaluation and mitigation strategy (REMS). Extended-release (ER) and long-acting (LA) opioid analgesics. 2013 April 15. Available at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf>. Accessed October 29, 2013.
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- Zogenix. Investors. News Release. Zogenix receives FDA approval for Zohydro<sup>(TM)</sup> ER (hydrocodone bitartrate) extended-release capsules. 2013 October 25. Available at <http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&ID=1868848&highlight=>. Accessed October 28, 2013.
- Zogenix receives FDA approval of new formulation of Zohydro<sup>®</sup> ER [press release on the internet]. San Diego (CA): Zogenix Inc.; 2015 Jan 30 [cited 2015 Feb 8]. Available at: <http://www.zogenix.com/content/news/index.php>
- Zohydro ER prescribing information. Zogenix, Inc. San Diego, CA. January 2015.

Last reviewed/updated: 4/6/15



**Line zolid (Zyvox®) tablets & Zyvox® (line zolid) oral suspension  
Prior Authorization Criteria  
Drug Protocol Management**

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**Linezolid (Zyvox®) tablets & Zyvox® (linezolid) oral suspension**

- **Quantity Limit**
  - **Tablets: 56 tablets/90 days**
  - **Oral suspension: 1800 mL (12 bottles)/90 days**

**How do I obtain a prior authorization for Zyvox®?**

- Download a prior authorization fax form & send to CVS/caremark at (866) 255-7569 (Medicaid), (855) 245-2134 (Exchange), (888) 836-0730 (Commercial).
- Contact CVS/caremark at (877) 433-7643 (Medicaid), (855) 582-2022 (Exchange), (800) 294-5979 (Commercial) for questions.

**Approval Criteria\***

- Patient was started on Zyvox® therapy in the hospital or other inpatient facility
- OR**
- Patient has a documented blood, sputum, tissue or urine culture positive for vancomycin-resistant Enterococcus (VRE)
- OR**
- Patient has a documented blood, sputum, tissue or urine culture positive for methicillin-resistant Staphylococcus (MRSA) and treatment with vancomycin is not an option (e.g. lack of IV access, etc.)
- OR**
- Patient currently has a complicated skin or skin structure infection with no concomitant osteomyelitis where a culture cannot be obtained (e.g. closed wound infections, diabetic foot infections, cellulitis infections, etc.) **and** patient has a history of MRSA infections

\* Note: weekly monitoring of patient's complete blood count (CBC) is required for treatment durations exceeding 2 weeks.

**References**

- Zyvox® [package insert]. New York, NY; Pfizer, Inc.; 2014 Jan.
- Stevens DL, Bisno AL, Chambers HF, Everett ED, Dellinger P, Goldstein EJC, et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft-Tissue Infections. IDSA Guidelines. CID. 2005;41:1373-406.
- Lipsky BA, Berendt AR, Cornia PB, Pile JC, Peters EJG, Armstrong DG, et al. 2012 IDSA Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections. CID. 2012;54(12):132-73.
- Mandell LA, Wunderink RG, Anzueto A, Bartlett JG, Douglas Campbell G, Dean NC, et al. IDSA/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults. CID. 2007;44:S27-72.
- Liu C, Bayer A, Cosgrove SE, Daum RS, Fridkin SK, Gorwitz RJ, et al. Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *Staphylococcus aureus* infections in adults and children. CID. 2011;52:1-38.

Last reviewed/updated: 8/3/15



**Zolinza<sup>®</sup> (vorinostat) Capsules  
Prior Authorization Criteria  
Drug Protocol Management**

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**How to I obtain Zolinza?**

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/caremark at (866) 814-5506 for questions

**Zolinza (vorinostat) 100mg capsules**

*NHP allows 120 capsules per 30 days*

**Recommendation is to not override this quantity limit.**

**For requests for Zolinza (vorinostat) exceeding 120 capsules per 30 days, please review with a pharmacist.**

**Pharmacist Note:**

*FDA labeled indication:* Treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent, or recurrent disease while on or following two systemic therapies.

*Recommended Dose:* 400mg ORALLY once daily with food; if intolerant to therapy, the dose may be reduced to 300mg orally once daily with food. If necessary, the dose may be further reduced to 300mg orally once daily with food for 5 consecutive days each week. Hepatic dosing adjustments are also required.



**Global Criteria**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

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**Approval Criteria:**

- Patient has tried and failed all available appropriate formulary medications. Documentation including drug name, dose, and duration of therapy required.

**OR**

- Patient has condition for which there are no other formulary alternatives.

**AND**

- Patient is using the requested medication for an FDA-approved indication or an indication supported in the compendia of current literature.

**AND**

- Patient age falls within the manufacturer's prescribing information.

Last reviewed/updated: 4/6/16



**Global Criteria**  
**Post Limit Prior Authorization Criteria**  
**Drug Protocol Management**

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**Approval Criteria:**

- The requested dose is within the maximum dose set by the FDA.

**OR**

- The patient will be using the requested quantity for titration purposes which will be completed within three months with the final titrated dose not exceeding the maximum dose set by the FDA.

**AND**

- The dose requested cannot be achieved using a higher strength of the requested drug.

Last reviewed/updated: 4/6/16



**Mandatory Generic  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

- Patient has tried and failed the generic formulation of the requested drug for the current indication.

**AND**

- Patient has documented intolerance, inadequate response, or treatment failure with the generic formulation of the requested medication.

Last reviewed/updated: 4/6/16



**Long Acting Narcotics: Post Limit  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

NHP will approve the request to exceed the quantity limit if the following conditions are met:

- Documentation has been provided noting the total daily dose of the requested medication, including full prescription directions with dose, frequency, and duration and one of the following:
  - The requested medication is being used to treat end-stage terminal illness.OR
  - The patient has seen a pain specialist or oncologist in the past 6 months or the patient has a scheduled appointment to be seen by a pain specialist or oncologist within the next three months and dose consolidation is not an option for the patient.

Last reviewed/updated: 9/6/16



**Long Acting Narcotics: oxycodone ER (Compare to OxyContin®) /OxyContin® (oxycodone ER) 60mg tablets; oxycodone ER (Compare to OxyContin®)/ OxyContin® 80mg tablets  
Post Limit Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

NHP will approve the request to exceed the quantity limit if the following conditions are met:

- Documentation has been provided noting the total daily dose of the requested medication, including full prescription directions with dose, frequency, and duration and one of the following:
  - The requested medication is being used to treat end-stage terminal illness.OR
  - The requested medication is being prescribed up to three times dailyAND
  - The patient has seen a pain specialist or oncologist in the past 6 months or the patient has a scheduled appointment to be seen by a pain specialist or oncologist within the next three months and dose consolidation is not an option for the patient.

Last reviewed/updated: 9/6/16



**Nonsedating Antihistamine Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

- NHP will approve the request to exceed the quantity limit if the diagnosis or indication is allergic asthma
- OR**
- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits and documentation for medical necessity to exceed the quantity limit has been provided.

Last reviewed/updated: 9/6/16



**Lyrica Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

**Lyrica (pregabalin) capsules**

**25mg, 50mg, 75mg, 100mg, 150mg, & 200mg**

**NHP allows 90 capsules per 30 days**

NHP will approve the request to exceed the quantity limit if the quantity requested is for dose titration  
OR

The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits and documentation of medical necessity to exceed the quantity limit has been provided.

**Lyrica (pregabalin) capsules**

**225mg & 300mg**

**NHP allows 60 capsules per 30 days**

NHP will approve the request to exceed the quantity limit if the dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits and documentation of medical necessity to exceed the quantity limit has been provided.

**Lyrica (pregabalin) 20mg/mL oral solution**

**NHP allows up to 900 mL per 30 days**

NHP will approve the request to exceed the quantity limit if the dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits and documentation of medical necessity to exceed the quantity limit has been provided.





**Cesamet Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

NHP will approve the request to exceed the quantity limit if the prescriber has provided documentation of the chemotherapy regimen and if the request is for up to 6 tablets for each day of chemotherapy and up to 6 tablets daily for up to 2 days after the completion of chemotherapy.

Pharmacist Note: The recommended dose of Cesamet is 1 or 2mg twice daily. It may be administered up to three times daily throughout the course of chemotherapy (up to 6mg/day) and may be continued for up to 48 hours after the last dose of chemotherapy if needed. Additionally, a dose of 1 or 2 mg the night before may also be useful.

Last reviewed/updated: 9/6/16



**Antimigraine/Triptan Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

NHP will approve requests to exceed the quantity limit if the following conditions are met:

- The patient currently has a headache (acute migraine) or cluster headache and needs a one-time override.
- The patient currently experiences 2 or more migraine headaches per week, takes medication for headache prophylaxis such as beta-blockers (propranolol, atenolol, metoprolol, etc.), tricyclic antidepressants (amitriptyline, etc.), calcium channel blockers (verapamil, etc.), anticonvulsants (depakote, topiramate), etc.], provides documentation of therapy, and has greater than 6 attacks per month.
  - If the patient has greater than 12 attacks per month, the patient must be followed by a headache specialist, neurologist, or had an appointment with a specialist within the past year for approval.

Last reviewed/updated: 9/6/16



**SNRI Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

**venlafaxine 25mg, 37.5mg, 50mg, 75mg, & 100mg tablets**

NHP allows 90 tablets per 30 days, when approved for Step Therapy

NHP will approve the request to exceed the quantity limit if the member requires a short term quantity limit override to allow for dose titration.

**venlafaxine SR 37.5mg & 75mg tablets**

NHP allows 60 tablets per 30 days, when approved for Step Therapy

NHP will approve the request to exceed the quantity limit if the member requires a short term quantity limit override to allow for dose titration.

**venlafaxine SR 150mg tablets**

NHP allows 60 tablets per 30 days, when approved for Step Therapy

NHP will approve the request to exceed the quantity limit if the member has tried and had an inadequate response to 300mg daily.

**Venlafaxine SR 225mg tablets**

NHP allows 30 tablets per 30 days, when approved for Step Therapy

NHP will approve the request to exceed the quantity limit if the member has tried and had an inadequate response to 300mg daily.

**venlafaxine SR 37.5mg & 75mg capsules**

NHP allows 60 capsules per 30 days

NHP will approve the request to exceed the quantity limit if the member requires a short term quantity limit override to allow for dose titration.

**venlafaxine SR 150mg capsules**

NHP allows 60 capsules per 30 days

NHP will approve the request to exceed the quantity limit if the member has tried and had an inadequate response to 300mg daily.

### **duloxetine 20mg capsules**

NHP allows 60 capsules per 30 days, when approved for Step Therapy

NHP will approve the request to exceed the quantity limit if the member requires a short term quantity limit override to allow for dose titration.

### **duloxetine 30mg capsules**

NHP allows 30 capsules per 30 days, when approved for Step Therapy

NHP will approve the request to exceed the quantity limit if the member requires twice daily dosing or a short-term override to allow for dose titration.

### **Pristiq (desvenlafaxine succinate SR) 100mg tablets**

NHP allows 30 tablets per 30 days, when approved for Step Therapy

NHP will approve the request to exceed the quantity limit if the member requires a daily dose of 200mg and has had an inadequate response to 150 mg daily.

\* **Pharmacist's note:** Doses up to 400mg daily have been studied in clinical trials with some efficacy, however no additional benefit was demonstrated at doses greater than 50 mg/day and adverse events and discontinuations were more frequent at higher doses. QL overrides, when approved, should be offered in 50mg increments (2<sup>nd</sup> copays may be waived). Discuss provider rationale for not considering other therapeutic options beyond 200mg daily.

### **Khedeza (desvenlafaxine SR) 100mg tablets, desvenlafaxine SR 100mg tablets, & desvenlafaxine succinate/fumarate 100mg tablets:**

NHP allows 30 tablets per 30 days, when approved for Step Therapy

NHP will approve the request to exceed the quantity limit if the member requires a daily dose of 200mg and has had an inadequate response to 150 mg daily.

\* **Pharmacist's note:** Doses up to 400mg daily have been studied in clinical trials with some efficacy, however no additional benefit was demonstrated at doses greater than 50 mg/day and adverse events and discontinuations were more frequent at higher doses. QL overrides, when approved, should be offered in 50mg increments (2<sup>nd</sup> copays may be waived). Discuss provider rationale for not considering other therapeutic options beyond 200mg daily.



**SSRI Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

**Citalopram 10, 20, 40mg tablets; fluoxetine 10mg & 20mg capsules; fluoxetine 10mg tablets; fluvoxamine 25mg & 50mg tablets; fluvoxamine ER 100mg & 150mg capsules (*compare to Luvox CR*); paroxetine HCL 10mg, 20mg, 30mg, & 40mg tablets; paroxetine ER 12.5mg, 25mg, & 37.5mg tablets; Pexeva (paroxetine mesylate) 30mg tablets; sertraline 25mg, 50mg, & 100mg tablets; Brisdelle 7.5mg capsules**

**fluvoxamine 100mg tablets**

NHP allows 90 tablets per 30 days

NHP will approve a request to exceed the quantity limit if the member tried and had an inadequate response to 300mg daily.

**escitalopram (compare to Lexapro®) 5mg tablets**

NHP allows 30 tablets per 30 days, when approved for Step Therapy

NHP will approve a request to exceed the quantity limit if the total daily dose is 7.5mg daily OR if the drug cannot be consolidated so that the quantity prescribed is within the allowed quantity limits AND documentation for medical necessity to exceed the quantity limit has been provided.

**escitalopram (compare to Lexapro®) 10mg tablets**

NHP allows 30 tablets per 30 days, when approved for Step Therapy

NHP will approve a request to exceed the quantity limit if the total daily dose is 15mg daily OR if the drug cannot be consolidated so that the quantity prescribed is within the allowed quantity limits AND documentation for medical necessity to exceed the quantity limit has been provided.

**escitalopram (compare to Lexapro®) 20mg tablets**

NHP allows 45 tablets per 30 days, when approved for Step Therapy

NHP will approve a request to exceed the quantity limit if the total daily dose is 40mg daily OR if the drug cannot be consolidated so that the quantity prescribed is within the allowed quantity limits AND documentation for medical necessity exceed the quantity limit has been provided.

**Pexeva (paroxetine mesylate) 10mg tablets**

NHP allows 30 tablets per 30 days, when approved for Step Therapy

NHP will approve a request to exceed the quantity limit if the total daily dose is 15mg daily OR if the drug cannot be consolidated so that the quantity prescribed is within the allowed quantity limits AND documentation for medical necessity to exceed the quantity limit has been provided.

**Pexeva (paroxetine mesylate) 20mg tablets**

NHP allows 30 tablets per 30 days, when approved for Step Therapy

NHP will approve a request to exceed the quantity limit if the total daily dose is 50mg daily or if the patient is being titrated 20mg tablets. NHP will also approve a request to exceed the quantity limit if the drug cannot be consolidated so that the quantity prescribed is within the allowed quantity limits and documentation for medical necessity to exceed the quantity limit has been provided.

**Pexeva (paroxetine mesylate) 40mg tablets**

NHP allows 30 tablets per 30 days, when approved for Step Therapy

NHP will approve a request to exceed the quantity limit if the total daily dose is 60mg daily OR if the drug cannot be consolidated so that the quantity prescribed is within the allowed quantity limits AND documentation for medical necessity to exceed the quantity limit has been provided.



**Terbinafine tablets & Lamisil granules Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

**Terbinafine tablets 250mg**

**NHP allows 30 tablets per 30 days and 84 tablets per year**

NHP will approve for requests to exceed the quantity limit if the request is for a one-month continuation of treatment due to extensive toenail onychomycosis infection for a member who has received a 3-month course of therapy.

Last reviewed/updated: 9/6/16



**Topical Immunomodulators Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

NHP will approve the request to exceed the quantity limit if the patient's affected areas include arms, legs, chest, back and the affected area requires more than 30 grams over 30 days.

Last reviewed/updated: 9/6/16





**Amitiza® (lubiprostone) & Linzess® (linaclotide) Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

Amitiza® 8 mcg capsules

NHP allows 60 capsules per 30 days

NHP will approve the request to exceed quantity limit if the diagnosis is either chronic idiopathic constipation (CIC) or opioid-induced constipation and the member has moderate or severe liver impairment (i.e., Child-Pugh Class B or Class C).

Pharmacist Notes (Amitiza®):

Recommended Dosage (normal hepatic function):

Chronic idiopathic constipation: 24 mcg capsule orally twice daily

Opioid-induced constipation with chronic, non-cancer pain: 24 mcg capsule orally twice daily

IBS-C: 8 mcg capsule orally twice daily

Dosage Adjustments (hepatic impairment):

Chronic idiopathic constipation

- moderate impairment (Child-Pugh Class B): 16 mcg twice daily; titration may occur if tolerated and inadequate response after an appropriate treatment interval. Doses can be escalated to full dosing with appropriate monitoring of patient response.
- severe impairment (Child-Pugh Class C): 8 mcg twice daily; titration may occur if tolerated and inadequate response.

Opioid-induced constipation with chronic, non-cancer pain:

- moderate impairment (Child-Pugh Class B): 16 mcg twice daily; titration may occur if tolerated and inadequate response after an appropriate treatment interval. Doses can be escalated to full dosing with appropriate monitoring of patient.
- severe impairment (Child-Pugh Class C): 8 mcg twice daily; titration may occur if tolerated and inadequate response.  
Doses can be escalated to full dosing with appropriate monitoring of patient response.

#### IBS-C:

- moderate impairment (Child-Pugh Class B): No dosage adjustment is required.
- severe impairment (Child-Pugh Class C): 8 mcg once daily; titration may occur if tolerated and inadequate response after an appropriate treatment interval. Doses can be escalated to full dosing with appropriate monitoring of patient response.

Last reviewed/updated: 9/6/16



**Itraconazole capsules & Sporanox® oral suspension Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

**Itraconazole 100 mg capsules**

**NHP allows 60 capsules per 30 days and 170 capsules per year**

NHP will approve a request to exceed quantity limit if the indication or diagnosis for itraconazole therapy is for Blastomycosis, Histoplasmosis, or Aspergillosis.

Last reviewed/updated: 9/6/16



**Suboxone®, Zubsolv®, & Bunavail® Quantity Limit Program**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

**Approval Criteria:**

Drug	Quantity per 30 days
buprenorphine/naloxone sublingual <u>tablets</u> ( <i>Compare to Suboxone®</i> )	<ul style="list-style-type: none"> <li>• 90 tablets of 2mg/0.5mg</li> <li>• 90 tablets of 8mg/2mg</li> </ul>
Suboxone® (buprenorphine/naloxone) sublingual <u>film</u>	<ul style="list-style-type: none"> <li>• 90 SL films of 2mg/0.5mg</li> <li>• 60 SL films of 4mg/1mg</li> <li>• 90 SL films of 8mg/2mg</li> <li>• 60 SL films of 12mg/3mg</li> </ul>
Zubsolv® (buprenorphine/naloxone) sublingual <u>tablets</u>	<ul style="list-style-type: none"> <li>• 60 tablets of 1.4mg/0.36mg</li> <li>• 60 tablets of 5.7mg/1.4mg</li> <li>• 60 tablets of 8.6mg/2.1mg</li> </ul>
Bunavail® (buprenorphine/naloxone) buccal <u>film</u>	<ul style="list-style-type: none"> <li>• 30 units of 2.1mg/0.3mg film</li> <li>• 90 units of 4.2mg/0.7mg film</li> <li>• 30 units of 6.3mg/1.0mg film</li> </ul>

Prescriptions for buprenorphine/naloxone SL tablets (*Compare to Suboxone®*), Suboxone SL film, Zubsolv SL tablets, and Bunavail® buccal film will adjudicate if the quantity limit has not been exceeded and, when applicable, a prior authorization has been approved. If the QL is exceeded, messages are sent back to the pharmacy and the claim will not process.

Members and/or prescribers can request a **clinical review** if the claim is denied.

**Criteria:**

- A. The member's dose of buprenorphine/naloxone being tapered down to allow 30mg or less per day  
**OR**  
 B. Prior attempts have been made to titrate the member down to 90 tablets per 30 days and the member has relapsed

Note: Recommended dosing is 16mg/4mg of Suboxone daily. Clinical studies have shown that 16mg/4mg of Suboxone is a clinically effective dose compared with placebo and indicate that doses as low as 12mg/3mg may be effective in some patients. The dosage of Suboxone should be adjusted in increments/decrements of 2mg/0.5mg or 4mg/1mg to a level that holds the patient in treatment and suppresses opioid withdrawal effects. This is likely to be in the range of 4mg/1mg to 24mg/6mg per day depending on the individual. The recommended target dosage of

Suboxone film during maintenance is 16 mg/4 mg buprenorphine/naloxone/day as a single daily dose. Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage.

Note: Bunavail buccal film is indicated for maintenance treatment. The recommended target dosage of Bunavail buccal film is 8.4/1.4 mg per day as a single daily dose. Bunavail should be adjusted in increments/decrements of 2.1/0.3 mg to a level that holds the patient in treatment and suppresses opioid withdrawal signs and symptoms. The maintenance dose of Bunavail buccal film is generally in the range of 2.1/0.3 mg to 12.6/2.1 mg per day depending on the individual patient. Dosages higher than this have not been demonstrated to provide any clinical advantage.

#### References:

1. Suboxone sublingual film [package insert]. Richmond (VA): Reckitt Benckiser Pharmaceuticals, Inc.; 2014 Apr.
2. Buprenorphine HCl and naloxone HCl sublingual tablet [package insert]. Hauppauge (NY: Amneal Pharmaceuticals of NY; 2015 Feb.
3. Zubsolv [package insert]. Wilmington (NC): Orexo US, Inc.; 2014 Dec.
4. Bunavail® [package insert]. Raleigh (NC): BioDelivery Sciences International Inc.; 2014 Jun.

Last reviewed/updated: 4/25/16



**Hypnotics Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

**Zaleplon 10mg tablets**

**NHP allows 30 units per 30 days**

NHP will approve requests to exceed the quantity limit if the dose being requested is 20mg daily, the member is less than 65 years of age, and the patient has had an inadequate response with zaleplon 10mg.  
Last reviewed/updated: 9/6/16



**HMG Co-A Reductase Inhibitors Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

**Lovastatin 10mg & 20mg, pravastatin, Altoprev, Crestor, fluvastatin 20mg, Lescol XL, & Livalo:**

**NHP allows 30 tablets/capsules per 30 days**

NHP will approve the request to exceed the quantity limit if the patient is receiving a dose that is administered once-daily that requires two different strengths of the medication.

**fluvastatin 40mg; lovastatin 40mg; simvastatin; atorvastatin; Liptruzet; Vytorin; & Zetia:**

NHP will approve the request to exceed the quantity limit if the dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits and if documentation for medical necessity to exceed the quantity limit has been provided.

Last reviewed/updated: 9/6/16



**Atypical Antipsychotics Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

**clozapine 25mg, 50mg, 100mg tablets**

Daily dose (target): 300mg to 450mg daily; with titration doses up to 900mg (max) daily may be warranted

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**risperidone oral tablets & ODT formulations:**

Effective dosing range: 0.5mg to 16mg per day depending on diagnosis.

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**risperidone oral solution:**

Effective dosing range: 0.5mg to 16mg per day depending on diagnosis.

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The patient is unable to swallow oral tablets or use the orally-disintegrating tablet (ODT) formulation
- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**olanzapine tablets & ODT:**

Daily dosing recommendation: 2.5mg to 20mg; however higher doses may be warranted with dose titration

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.



**quetiapine tablets:**

Recommended daily dose range: 150mg to 800 mg daily, depending upon diagnosis

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Seroquel XR:**

Recommended daily dose range: 150mg to 800 mg daily, depending upon diagnosis

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**ziprasidone capsules:**

Daily dosing recommendation: 20mg to 80 mg twice daily (100mg twice daily has been studied in trials)

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Abilify tablets & ODT:**

Recommended dose range: 5mg to 15mg daily (diagnosis & age dependent); max of 30mg daily

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Abilify oral solution:**

Recommended dose range: 5mg to 15mg daily (diagnosis & age dependent); max of 30mg daily

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The patient is unable to swallow oral tablets or use the orally-disintegrating tablet (ODT) formulation
- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

### **Invega 1.5mg & 3mg tablets:**

Recommended dose range: 3mg to 12mg daily (diagnosis & age-dependent)

NHP allows 30 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose is being titrated OR
- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits and documentation of medical necessity to exceed the quantity limit has been provided.

### **Invega 6mg tablets:**

Recommended dose range: 3mg to 12mg daily (diagnosis & age-dependent)

NHP allows 60 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

### **Invega 9mg tablets:**

Recommended dose range: 3mg to 12mg daily (diagnosis & age-dependent)

NHP allows 30 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

Note: Recommended dosing is 6 mg daily. Patients may begin therapy at this dose. Dose increases past 6 mg should be made only following clinical reassessment & should be made at intervals of > 5 days & increments of 3 mg/day. The maximum recommended dose is 12 mg/day.

### **Latuda 20mg, 40mg, 60 mg, & 120mg tablets:**

Recommended dosing range: 40mg to 160mg daily; max 160mg daily

NHP allows 30 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Latuda 80mg tablets:**

Recommended dosing range: 40mg to 160mg daily; max 160mg daily

NHP allows 60 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Saphris 5mg & 10mg SL tablets:**

Recommended daily dose range: 5mg to 10mg twice daily; max of 10mg twice daily

NHP allows 60 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Fanapt 1mg, 2mg, 4mg, 6mg, 8mg, 10mg, & 12mg tablets:**

Recommended target dose range: 12mg to 24 mg daily in two divided doses

NHP allows 60 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Rexulti 0.25mg, 0.5mg & 1mg tablets:**

Recommended target dose range: 2 to 4mg daily

NHP allows 60 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Rexulti 2mg, 3mg, & 4mg tablets:**

Recommended target dose range: 2 to 4mg daily

NHP allows 30 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Vraylar 1.5mg capsules:**

Recommended target dose range: 1.5mg to 6mg daily

NHP allows 60 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

**Vraylar 3mg, 4mg & 6mg:**

Recommended target dose range: 1.5mg to 6mg daily

NHP allows 30 units per 30 days

NHP will approve the request to exceed the quantity limit if the following criteria are met:

- The dose cannot be consolidated so that the quantity prescribed is within the allowed quantity limits
- Documentation of medical necessity to exceed the quantity limit has been provided.

Implemented: 11/05/07

Reviewed: 09/24/07; 09/21/09; 06/21/2010; 06/27/11; 11/24/14; 11/23/15 P&T Mtg

Updated: 7/21/08 (risperidone); 10/26/09 (drug file Invega 1.5mg); 02/03/12 (11/21/11 drug file olanzapine and 2/1/12 MHP notice of Zydis MSC override); 3/19/12 (Latuda 20mg tab 2/13/12 file); 12/01/12 (Latuda 120mg; 9/24/12 file); 03/01/13 (Update ST/QL programs; QL for clozapine 50mg tabs; increase risperidone ODT QLs; review in CCC); 7/22/13 (Abilify Maintena; 3/25/13 file); 11/4/13 (Latuda 60mg strength; 10/7/13 file); 06/08/15 (Abilify tabs generic; 5/18/15 file); 08/03/15 (Focalin XR 20mg generic; 07/13/15 file & Invega Trinza; 06/29/15); 10/01/15 (Abilify oral soln generic; 9/7/15 file & Invega tabs generic; 10/19/15 file) 6/22/16 P&T Mtg (add Rexulti and Vraylar)



**Short Acting Narcotics Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

NHP will approve requests to exceed a short-acting narcotic quantity limit if the following criteria are met:

- Documentation of the total daily dose of the requested medication, including full prescription directions with dose, frequency, and duration has been provided.
- The requested quantity is being used to treat end-stage terminal illness and the patient is currently being maintained on a long-acting opioid.  
If the patient has not been maintained on a long-acting opioid, rationale has been provided for why long-acting opioid cannot be used.
- The requested quantity is being used to treat end-stage terminal illness and the quantity is being requested for a first time titration of dose.

Additional titration dose requests are approved if the following are met:

- a. The patient is currently being maintained on a long-acting opioid or rationale has been provided for why long-acting opioid cannot be used.
- b. The dose requested is being consolidated if applicable.
- c. The patient has seen a pain specialist or oncologist in the past 6 months or the patient has a scheduled appointment to be seen by a pain specialist or oncologist within the next 3 months.



**Nasal Steroids Quantity Limit Program  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

Nasonex

NHP allows 1 inhaler per 30 days without Post Limit review.

NHP allows 2 inhalers per 30 days for one year if the patient has nasal polyps or if the patient requires higher doses (2 sprays/nostril twice daily) to achieve symptom relief.

budesonide nasal (Rhinocort Aqua)

NHP allows 1 inhaler per 30 days

NHP allows 2 inhalers per 30 days for one year if the member requires maximum dosing (3-4 sprays per nostril) to achieve symptom relief.

Last reviewed/updated: 9/6/16



**Oral Anticoagulants: Eliquis, Pradaxa, Xarelto Quantity Limit Program**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

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**Approval Criteria:**

Prescriptions for Xarelto 10 mg tablets will adjudicate if the allowed QLs have not been exceeded.

Prescriptions for Eliquis, Pradaxa, & Xarelto 15 mg and 20 mg tablets will adjudicate if the PA requirements have been met and the QLs have not been exceeded.

Eliquis® (apixaban) 2.5mg & 5mg tablets

NHP allows 60 tablets per 30 days (both strengths) for atrial fibrillation

Recommendation is not to override the QL

NHP allows 70 tablets for 35 days of the 2.5mg strength for DVT prophylaxis post-hip replacement surgery

Recommendation is not to override the QL

NHP allows 24 tablets per 12 days of the 2.5mg strength for DVT prophylaxis post-knee replacement surgery

Recommendation is not to override the QL

NHP allows 28 tablets per 7 days of the 5mg strength and 60 tablets per 30 days of the 5mg for strength for the Treatment of DVT/PE

Recommendation is not to override the QL

NHP allows 60 tablets per 30 days of the 2.5mg strength for reduction in the risk of DVT & PE

Recommendation is not to override the QL

Pradaxa® (dabigatran) 75mg & 150mg capsules

NHP allows 60 tablets per 30 days

Recommendation is not to override the QL

Savaysa® (edoxaban) 15mg, 30mg & 60mg tablets

NHP allows 30 tablets per 30 days

Recommendation is not to override the QL

Xarelto® (rivaroxaban) 10 mg tablets

NHP allows 35 tablets per 35 days; one fill per 365 days\*

\*NHP allows for a one-time one fill override if the requested medication is for DVT/PE prophylaxis due to a second orthopedic surgery (i.e., knee/hip replacement surgery) within a one-year time frame.

#### Xarelto® (rivaroxaban) 15 mg tablets

For treatment of DVT or PE and for the reduction of risk of recurrence of DVT or PE:

NHP allows 42 tablets per 21 days (initial therapy)

Recommendation is not to override this QL

For prevention of stroke/embolism in atrial fibrillation:

NHP allows 30 tablets per 30 days

Recommendation is not to override this QL

#### Xarelto® (rivaroxaban) 20 mg tablets

For treatment of DVT or PE and for the reduction of risk of recurrence of DVT or PE:

NHP allows 30 tablets per 30 days (continuation/maintenance therapy)

Recommendation is not to override this QL

For prevention of stroke/embolism in atrial fibrillation:

NHP allows 30 tablets per 30 days

Recommendation is not to override this QL

#### Xarelto® (rivaroxaban) Starter Pack (15mg & 20mg tablets)

For treatment of DVT or PE and for the reduction of risk of recurrence of DVT or PE:

NHP allows one (1) starter pack (#51 tablets per 30 days) once

Recommendation is not to override this QL

#### Dosing information:

For DVT prophylaxis, the recommended dose is 10 mg QD, starting at least 6 to 10 hours after surgery, once hemostasis has been established. The recommended duration of treatment is 35 days for hip replacement surgery & 12 days for knee replacement surgery; although extended therapy up to 35 days may be warranted. When used for the prevention of stroke or systemic embolism in atrial fibrillation, the dose is 20 mg QD with the evening meal. For non-valvular atrial fibrillation, rivaroxaban use should be avoided in patients with a CrCl < 15 mL/min. In addition, the dose should be adjusted to 15 mg daily for CrCl between 15 and 50 mL/min. For the prophylaxis of DVT following hip or knee replacement surgery, rivaroxaban use should be avoided in patients with severe renal impairment (CrCl < 30 mL/min). For the treatment of DVT or PE, the recommendation dose is 15 mg BID for the first 21 days, followed by 20 mg QD for the remaining treatment. The dosing for the reduction in risk of recurrence of DVT or PE is 20 mg QD. For the treatment of DVT or PE and reduction in risk of recurrence of DVT or PE, rivaroxaban should be avoided in patients with CrCl < 30 mL/min.





**HETLIOZ (tasimelteon)**  
**Prior Authorization Criteria**  
**Drug Protocol Management**

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**Approval Criteria:**

Coverage for HETLIOZ (tasimelteon) will be granted given all of the following conditions are met:

1. The member is completely blind and has a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24)  
**AND**
2. The prescriber is a sleep specialist or is being prescribed in consult with a sleep specialist who directly recommends its use  
**AND**
3. The member has had at least a one-month trial of timed melatonin administration that resulted in an inadequate response or adverse reaction  
**AND**
4. The member has had a side effect, allergy, or treatment failure with at least a one-month trial of ROZEREM (ramelteon) therapy  
**AND**
5. The quantity being prescribed does not exceed 30 capsules per 30 days

**Initial Approval Duration:**

If patient meets all of the above criteria, authorization for HetlioZ will be granted for 6 months (initial approval).

**Recertification:**

Documentation of improvement. Approve for 12 months.



**Weight Loss Medications: Alli (orlistat), Belviq (lorcaserin), Qsymia  
(phentermine/topiramate)**

**Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

- The member is 14 years of age or older.
- The member's BMI (Body Mass Index) is greater than or equal to 30kg/m<sup>2</sup>.

OR

The member's BMI (Body Mass Index) is greater than or equal to 27kg/m<sup>2</sup> but less than 30kg/m<sup>2</sup> and the member has at least one of the following conditions:

- Coronary heart disease;
- Type 2 diabetes mellitus;
- Obstructive sleep apnea;
- Obesity hypoventilation syndrome;
- Pseudotumor cerebri;
- Obesity related cardiomyopathy;
- Nonalcoholic steatohepatitis (NASH);

OR

- Presence of 3 or more of the following CV risk factors:
  - Hypertension (SBP>140 or DBP >90 or taking antihypertensive agents);
  - Low HDL cholesterol (<35 mg/dL);
  - Elevated LDL cholesterol (>160 mg/dL);
  - Impaired glucose intolerance (FPG 110 to 125 mg/dL);
  - Family history of premature CHD (MI or sudden death at or before 55 years of age in father or other male first-degree relative, or at or before 65 years of age in mother or other female first degree relative); or
  - Age > 45 in men and >55 in women;

AND

- The member has been an active participant in an outpatient weight loss (behavioral modification) program (i.e., nutritional counseling, psychological counseling, hospital-based weight loss program, prescribed diet plans, Weight Watchers, or on weight loss medications, etc.) for the previous 3 months.
- The patient has lost ≤5% of body weight or plateaued weight since being enrolled in the behavioral modification program in the past 3 months.
- The patient will be on a reduced calorie diet during treatment with the requested medication.

**Approval Criteria for Continuation of Therapy (previously approved by NHP or other insurance carrier):**

- The patient has lost  $\geq 5\%$  of body weight since initiation of the treatment with the requested medication  
OR
- The patient has lost  $< 5\%$  of body weight, but weight loss is being maintained (i.e., not gaining weight).

References:

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Reviewed & Revised: 9/25/06; 9/24/07; 09/21/0909; 09/27/10; 02/25/13 P&T Mtg

Reviewed: 09/22/08; 02/28/11; 02/27/12; 02/24/14 P&T

Updated: 06/03/13 (Remove Xenical Rx coverage; 04/2013 P&T discussion)



## Amitiza® (lubiprostone) & Linzess® (linaclotide) capsules

### Prior Authorization Criteria

### Drug Protocol Management

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#### Approval Criteria:

- The patient has a diagnosis of chronic idiopathic constipation (CIC) or constipation predominant irritable bowel syndrome (IBS-C).  
OR
- The request is for Amitiza (lubiprostone) for a patient with a diagnosis of opioid-induced constipation, and the patient is actively using opioid analgesics for chronic, noncancer-related pain.  
OR
- The patient has a diagnosis of chronic constipation (not otherwise specified) and all other causes of constipation have been ruled out (medication-induced constipation, gastrointestinal [GI] motility issues, GI obstruction, etc.).

AND

- The patient is at least 18 years of age.
- The patient has either been started and stabilized on the requested medication, excluding the use of samples.  
OR
- The patient has failed dietary and lifestyle modifications.
- The patient has experienced an allergy or side effect with or has had at least a 1-week trial resulting in treatment failure or inadequate response with at least two (2) different **laxative** agents such as saline, stimulant, bulk, or osmotic laxatives (e.g., milk of magnesia, lactulose, polyethylene glycol [PEG], psyllium, methylcellulose, magnesium citrate, senna, bisacodyl, etc)

#### References:

9. Amitiza™ [package insert] Sucampo Pharmaceuticals, Inc. Bethesda, MD, 2013 April.
10. FDA Approves New Prescription Drug for Adults for Treatment of Chronic "Idiopathic" Constipation. January 31, 2006. Available at: <http://www.fda.gov/bbs/topics/news/2006/NEW01305.html>.
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#### Linzess Program:

Implemented: 08/12/13 (NHP review); 04/07/14 Clinical Call Center review  
Reviewed: 06/24/13; 06/23/14 P&T Mtg

#### Amitiza Program:

Implemented: 06/01/07 (NHP review); 04/07/14 Clinical Call Center review  
Reviewed: 04/23/07; 06/21/10; 06/25/12 (dosing info); 06/23/14 P&T Mtg  
Reviewed & Updated: 06/16/08 (IBS-C indication); 06/15/09 (warnings); 06/27/11 (hepatic dosing); 06/24/13 P&T Mtg

#### Criteria Programs combined: 06/22/15 P&T Mtg

Reviewed: 6/27/16 P&T Mtg



## **Altabax (retapamulin) 1% ointment Prior Authorization Criteria Drug Protocol Management**

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### **Approval Criteria:**

- The patient has impetigo caused by, or suspected to be caused by, the *Staphylococcus aureus* (methicillin-susceptible isolates) or *Streptococcus pyogenes* species.

AND

- The patient has tried generic mupirocin ointment for the requested diagnosis.  
OR
- The patient had a side effect, allergy, or treatment failure with mupirocin ointment.

**\* Pharmacist's Note: mupirocin ointment is available without prior authorization; however, generic mupirocin cream requires a prior authorization**

### **References:**

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Reviewed: 02/25/08; 06/21/2010; 06/27/11; 06/25/12; 06/24/13; 06/23/14 6/27/16 P&T Mtg  
Reviewed & Updated: 06/15/09; 06/22/15 P&T Mtg  
Implemented: 04/15/08



**Topical Immunomodulators Post Limit  
Prior Authorization Criteria  
Drug Protocol Management**

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**Approval Criteria:**

- The requested medication will not be applied to the face, eyelids, groin, or diaper area.  
**AND**
- The requested medication will be applied to the arm(s), leg(s), chest, back or other areas.
- The approved quantity is dependent upon the patient's affected body surface area percentage.

Last reviewed/updated: 9/6/16