Actemra® (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®?
- 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® for an approvable indication
- Patient is ≥ 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 ≥ 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® for the approvable indication
- Patient is ≥ 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.

References


Last reviewed/updated: 4/6/2015
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 ≥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 (A/JC: 0 joints, 1–4 joints, or ≥5 joints). If a recommendation is noted to be irrespective of the A/JC or MD global, the recommendation was for children with an A/JC ≥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 anti-inflammatory drug; IV = intravenous; MTX = methotrexate; TNFα = tumor necrosis factor α.

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512
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 (≤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 anti-inflammatory drug; IV = intravenous; TNFα = tumor necrosis factor α.

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

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

- 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®, **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 ≥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/μL.

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

A. Psoriasis is less than “clear” or shows improvement per physician assessment, **and**
B. CD4+ T lymphocyte count is ≥ 250 cells/μL, **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® (dalfampridine)
Prior Authorization Criteria
Drug Protocol Management

Ampyra® (dalfampridine)

How do I obtain a prior authorization for Ampyra®?
- 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 ≥ 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:**

<table>
<thead>
<tr>
<th>Adult Dose</th>
<th>Pediatric Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking improvement in MS:</td>
<td>Safety and efficacy in patients under the age of 18 have not been established.</td>
</tr>
<tr>
<td>Extended-release oral tablet: 10 mg BID, taken approximately 12 hours apart, with or without food.</td>
<td></td>
</tr>
<tr>
<td>Note: 10 mg BID is the maximum recommended dose.</td>
<td></td>
</tr>
<tr>
<td>No additional benefit has been demonstrated at higher doses; however adverse events are increased at higher doses.</td>
<td></td>
</tr>
</tbody>
</table>

**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 (≤ 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:

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

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

How do I obtain a prior authorization for Botox®, Myobloc®, Dysport® or Xeomin®?
• 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®:
Approval for Botox® will be granted for the following conditions:
1. Achalasia
   a. Esophageal achalasia
   b. Internal anal sphincter (IAS) achalasia
2. Anal Fissure
3. Blepharospasm (≥ 12 years of age)*;(adult patients)§
   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*:†,‡,§
   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)†
15. Salivary hypersecretion
   a. Drooling in Parkinson’s disease
   b. Salivary fistula
16. Strabismus* (≥ 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**†
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 ≥ 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® 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® for this indication will be authorized when the following criteria have been met:
   1. The member is ≥ 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® 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® 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® for this indication will be authorized when the following criteria have been met:
   1. The member is ≥ 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® 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.

Last reviewed/updated: 6/4/2014
Brovana® (arformoterol) and Perforomist® (formoterol)
Prior Authorization Criteria
Drug Protocol Management

Brovana® (arformoterol) & Perforomist® (formoterol)
- Quantity limit of #60 vials per 30 days if approved.

How do I obtain a prior authorization for Brovana® or Perforomist®?
- 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®) and formoterol (Perforomist®) 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® (salmeterol/fluticasone), Foradil® (formoterol), Serevent® (salmeterol), Symbicort® (budesonide/formoterol), Dulera® (mometasone/formoterol), Arcapta™ Neohaler™ (indacaterol), Breo® Ellipta® (fluticasone furoate/vilanterol), Anoro Ellipta® (umeclidinium/vilanterol), etc.

References

Last reviewed/updated: 11/10/14
Carbaglu (carglumic acid)
Prior Authorization Criteria

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.
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 Zubsov® (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

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 ≥ 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 ≥ 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.
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

**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.

Total parenteral nutrition (TPN) and antibiotics or anti-infectives for injectable use are covered.

Topical compounds (e.g. cream, gel, lotion, ointment) are not covered if includes bulk powder 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.

Compounds for scar diminishing, cosmetic use, anti-aging, or compounds that contain Coenzyme Q10 (Ubiquinol), Collagenase (Santyl), Naltrexone, or Resveratrol are not covered.

Pharmaceutical compounding is the combining, mixing, or altering of ingredients to create a customized medication that is not otherwise commercially available for an individual patient in response to a licensed practitioner's prescription. The FDA does not allow the marketing of compounding drugs that were withdrawn or removed from the market due to lack of safety or effectiveness; or compounding finished drugs from bulk active ingredients that are not per FDA regulations; or compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. Compounding does not generally include mixing or reconstituting commercial products in accordance with the manufacturer's instructions or the product's approved labeling.\(^1\)
There may be situations where a compound prescription is necessary due to special patient needs for customized therapies. Health needs that commercially available prescription medicines cannot meet may include:

- drug shortages, the need to access drugs or dosage forms withdrawn from the market, or medication is discontinued by or generally unavailable from pharmaceutical companies, often because the medication is no longer profitable to manufacturer
- patient is allergic to certain preservatives, dyes or binders in commercially available medications (e.g., allergen-free medications)
- treatment requires tailored dosage strengths for patients with unique needs (e.g., an infant, non-standard doses, and parenteral nutrition)
- patient cannot ingest the medication in its commercially available form and the medication can be prepared in another form that the patient can ingest.
- medications require flavor additives to make them more palatable for some patients, most often, children.¹⁻⁸

There may be a need to fill the compound prescription more than once per month (necessity may include continuation of antibiotic therapy, stability of water-containing formulation is less than a month, dose adjustment).²⁻⁶⁻⁷

REFERENCES


Last reviewed/updated: 5/27/16
Daliresp® (roflumilast) Prior Authorization Criteria Drug Protocol Management

**Daliresp® (roflumilast)**
- Quantity Limit: 30 tablets per 30 days

**How do I obtain a prior authorization for Daliresp®?**
- 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® 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 **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**
• FDA approves new drug to treat chronic obstructive pulmonary disease [press release on the Internet]. Rockville (MD): Food and Drug Administration (US); 2011 Mar 1 [cited 2012 May]. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm244989.htm
Last reviewed/updated: 8/3/2015
Diclegis® (doxylamine succinate and pyridoxine hydrochloride)

Prior Authorization Criteria

Drug Protocol Management

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, acupressure, mint, licorice, etc. AND
- The patient has had an inadequate response to generic pyridoxine (vitamin B₆) 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


Last reviewed/updated:6/8/2015
Emsam® (selegeline) Prior Authorization Criteria Drug Protocol Management

Emsam® (selegeline)
- Quantity Limit: 30 patches/30 days

How do I obtain a prior authorization for Emsam®?
- 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 ≥ 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 ≥ 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®) 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.

References
  Last reviewed/updated: 1/12/15
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 ≥ 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 ≥ 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**

![Diagram](Image)

**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 1-5 or 2-5 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 (AUC; 0 joints, 1-4 joints, or >4 joints). If a recommendation is noted to be irrespective of the AUC or MD global, the recommendation was for children with an AUC >0 or an MD global >0, respectively. Adjunct systemic glucocorticoids (GCs) and/or intramuscular 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; TNFα = tumor necrosis factor α.

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512
**Appendix 2**

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

![Diagram showing treatment pathways for patients without active systemic features and varying degrees of synovitis.](image)

**Figure 2.** Treatment pathways for patients without active systemic features and varying degrees of synovitis. The Task Force Panel was asked to rate the appropriateness of therapies based on the total number of active joints (<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; TNFα = tumor necrosis factor α.

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

**References**

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 ≥ 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


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:
  o 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
  o 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:
  o 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
  o Bone metastases
  o A history of skeletal malignancy
  o Hypercalcemia
  o Primary hyperparathyroidism
  o 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.
References

  Last reviewed/updated: 1/12/15
Fulyzaq® (crofelemer) Prior Authorization criteria Drug Protocol Management

Fulyzaq® (crofelemer)
• Quantity limit: 60 tablets/30 days

How do I obtain a prior authorization for Fulyzaq®?
• 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 ≥ 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
• FULYZAQ Prescribing Information. Salix Pharmaceuticals, Inc. Raleigh, NC. February 2013.

Last reviewed/updated: 4/6/15
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:

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

Allowed quantity:
The quantity prescribed must not exceed 30 capsules per 30 days

Based upon FDA requirements published on May 14, 2012, the following 1st-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 1st 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 2nd-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 1st-dose monitoring procedures should be repeated for the 2nd 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 ≥500 ms
- Treatment with Class Ia or Class III anti-arrhythmic drugs
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.

<table>
<thead>
<tr>
<th>First-Line Agents*</th>
<th>Second-Line Agents+</th>
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</thead>
<tbody>
<tr>
<td>Follistim AQ</td>
<td>Gonal- F RFF</td>
</tr>
<tr>
<td>Cetrotide</td>
<td>Bravelle</td>
</tr>
<tr>
<td>Menopur</td>
<td>Ganirelix</td>
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</tbody>
</table>
*Brand Name: Second tier copay +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.

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
All growth hormone products are considered specialty products; dispensing is available from NHP’s preferred specialty pharmacy provider CVS/caremark. Omnitrope® (somatropin) and Tev-Tropin® (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® or Tev-Tropin®.

<table>
<thead>
<tr>
<th>First-Line Agents</th>
<th>Second-Line Agents</th>
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<tbody>
<tr>
<td>(Brand-name, second tier copay if approved)</td>
<td>(Brand-name, third tier copay, if approved)</td>
</tr>
<tr>
<td>Omnitrope® (somatropin)</td>
<td>Genotropin® (somatropin)</td>
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<td>Tev-Tropin® (somatropin)</td>
<td>Humatrope® (somatropin)</td>
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<td>Serostim® (somatropin)</td>
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<td>Zomaclon® (somatropin)</td>
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<td></td>
<td>Zorbtive® (somatropin)</td>
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</tbody>
</table>

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.

Approval Criteria
Approval of growth hormone will be granted if the patient meets any of the criteria outlined below.

A. Children Diagnosed With Acquired Growth Hormone Deficiency
Coverage of growth hormone is recommended for children who meet the following criteria:
1) The patient must be evaluated by a pediatric endocrinologist
2) The patient’s baseline height must be < the third percentile (i.e. > 2 standard deviations [SD] below the mean for gender and age)
3) The patient’s growth velocity must be below the 25th percentile for age and gender, unless diagnosed with an abnormality in pubertal development
4) The patient must have a documented growth hormone deficiency, as defined by a diminished serum growth hormone response to stimulation testing of < 10 ng/ml. The results of at least two stimulation tests are required.

For children who meet all but #4 of the criteria listed above, coverage of growth hormone on a 12-month trial basis is recommended, provided that:
- Two provocative growth hormone tests must still be documented to show stimulated serum concentrations >10 ng/ml
- A pediatric endocrinologist must certify that 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) and that the child has a condition for which growth hormone is effective (or will possibly be effective during a trial of therapy)
A pediatric endocrinologist must certify that, 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)

Authorization for continued therapy will be based on an adequate clinical response, defined as either 1) a growth rate that doubles in the first year of therapy, or 2) growth increases by ≥ 3 cm/year (i.e. in addition to baseline growth)

B. Adult Growth Hormone Deficiency
Coverage of growth hormone is recommended for patients who meet the following criteria:
1) The patient must be evaluated by an endocrinologist
2) The patient must have a documented diagnosis of growth hormone deficiency syndrome that is one of the following:
   a. Adult onset: growth hormone deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma
   b. Childhood onset
3) The patient must have one of the following:
   a. A negative response to one standard growth hormone stimulation test [maximum peak of ≤ 5 ng/ml measured by radioimmunoassay (polyclonal antibody) or < 2.5 ng/ml measured by immunoradiometric assay (monoclonal antibody)]
   b. Two or more documented pituitary hormone deficiencies and a serum IGF-I < 84 ug/liter (11nmol/liter) using the Esoterix Endocrinology competitive binding RIA (other causes of low serum IGF-I must be excluded before using IGF-I as a marker of growth hormone deficiency)

C. Patients who have undergone brain radiation
Coverage of growth hormone is recommended for patients who have undergone brain radiation that has affected the normal functioning of the pituitary gland.

D. Turner’s syndrome
Coverage of growth hormone 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.

E. Short Stature in children with Noonan Syndrome
Coverage of growth hormone is recommended for short stature in children with Noonan syndrome. Patients must be evaluated by a pediatric endocrinologist. Evaluation of growth hormone secretion is not necessary.

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

G. Congenital hypopituitarism
Coverage of growth hormone is recommended for infants or children with congenital hypopituitarism. Patients must be evaluated by a pediatric endocrinologist and meet the criteria for children above.
H. Prader-Willi syndrome
Coverage of growth hormone 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. Note that growth hormone is NOT recommended for use in children with growth failure due to Prader-Willi syndrome who also have severe obesity, uncontrolled diabetes, untreated severe obstructive sleep apnea (OSA), active cancer, or active psychosis.

I. Short children born small for gestational age (SGA) or with intrauterine growth retardation (IUGR), including Silver-Russell syndrome.
Coverage of growth hormone is recommended for patients who meet the following criteria:
1) The patient must be evaluated by a pediatric endocrinologist
2) The patient must have been born SGA, which is defined as birth weight and/or birth length that is > 2 SD below the mean for gestational age and gender, and did not have significant catch-up growth by age 2
3) The patient must be ≥ 2 years and ≤ 8 years of age or > 8 years of age and prepubertal
4) The patient’s baseline height must be < the third percentile (i.e. > 2 SD below the mean for gender and age)

J. AIDS Wasting Syndrome
Coverage of growth hormone is recommended for patients who meet the following criteria:
1) The patient must be HIV-positive and have AIDS-wasting syndrome
2) The patient must have one of the following: documented, unintentional weight loss of ≥ 10% from baseline; weight < 90% of the lower limit of ideal body weight; or body mass index (BMI) ≤ 20 Kg/m²
3) The patient must be able to consume or be fed, through parenteral or enteral feedings, ≥ 75% of energy requirements based on current body weight
4) The patient must have been on antiretroviral therapy for ≥ 30 days prior to beginning growth hormone therapy and will continue antiretroviral therapy throughout the course of growth hormone therapy

K. HIV-associated failure to thrive
Coverage of growth hormone is recommended for children aged < 17 years with HIV-associated failure to thrive who meet the following criteria:
1) The patient must be able to consume or be fed, through parenteral or enteral feedings, ≥ 75% of maintenance energy requirements based on current body weight
2) The patient must have been on antiretroviral therapy for ≥ 30 days prior to beginning growth hormone therapy and will continue antiretroviral therapy throughout the course of growth hormone treatment

L. Short-stature homeobox-containing gene deficiency (SHOX-D)
Coverage of growth hormone is recommended for children with short stature associated with short-stature homeobox-containing gene deficiency (SHOX-D), demonstrated by chromosome analysis. Patients must be evaluated by a pediatric endocrinologist. Evaluation of growth hormone secretion is not necessary.

Exclusions
Coverage of Serostim™ is not recommended in the following circumstances: HIV-infected patients with alterations in body fat distribution (e.g., increased abdominal girth, buffalo hump).
Coverage of growth hormone is not recommended in the following circumstances:

A. Constitutional delayed growth and development
B. Idiopathic Short Stature
C. Familial short stature (normal short stature, non-growth-hormone-deficient short stature)
D. Down's syndrome
E. Corticosteroid-induced short stature, including chronic glucocorticoid-dependent conditions (e.g., asthma, inflammatory bowel disease, juvenile rheumatoid arthritis, & post renal, heart, liver, or bone marrow transplantation)
F. Kidney transplant patients with a functional renal allograft
G. Congenital adrenal hyperplasia
H. Liver transplantation
I. Bone marrow transplantation without total body irradiation (cranial radiation)
J. Bony dysplasias (achondroplasia, hypochondroplasia)
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
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
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
AA. Fibromyalgia.
BB. Cystic fibrosis
CC. Cerebral palsy

References


Last reviewed/updated: 8.3.15
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.

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 compensated 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.

† Treatment of decompensated cirrhosis, including Child-Turcotte-Pugh class B or C, will be considered on a case by case basis and patient should be referred to a highly experienced Hepatitis C clinician (ideally in a liver transplant center).

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

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Treatment History</th>
<th>Regimen</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Treatment Naïve</td>
<td>Without cirrhosis</td>
<td>Daily Zepatier (without baseline NS5A polymorphisms) <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Daily Harvoni <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>HCV RNA &lt;6,000,000 IU/ml (8 weeks)*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>HCV RNA &gt;6,000,000 IU/ml (12 weeks)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td>With compensated cirrhosis</td>
<td></td>
<td>Daily Zepatier (without baseline NS5A polymorphisms) <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Daily Harvoni <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td>1a</td>
<td>Treatment Experienced</td>
<td>Prior PEG-IFN + RBV failed</td>
<td>Without cirrhosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Daily Harvoni <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>With compensated cirrhosis</td>
<td>Daily Zepatier (without baseline NS5A polymorphisms) <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Daily Harvoni + weight-based ribavirin <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td>Prior sofosbuvir plus RBV +/- PEG-INF regimen failed</td>
<td>Without cirrhosis</td>
<td>Daily Harvoni + weight-based ribavirin <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>With compensated cirrhosis</td>
<td>Daily Harvoni + weight-based ribavirin <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td>Prior NS3 PI (telaprevir, boceprevir, or simeprevir) + PEG-INF/RBV regimen failed</td>
<td>Without cirrhosis</td>
<td>Daily Harvoni <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>With compensated cirrhosis</td>
<td>Daily Harvoni <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td></td>
<td>Prior simeprevir + sofosbuvir regimen failed</td>
<td>Without cirrhosis</td>
<td>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. <strong>Class IIb, Level C</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>With compensated cirrhosis</td>
<td>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. <strong>Class II, Level C</strong></td>
</tr>
<tr>
<td></td>
<td>Prior NSSA inhibitor regimen</td>
<td>Without cirrhosis</td>
<td>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. <strong>Class IIb, Level C</strong></td>
</tr>
</tbody>
</table>
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. **Class IIb, Level C**

### Treatment Naive

<table>
<thead>
<tr>
<th>Genotype 1b</th>
<th>Treatment Experienced</th>
<th>Without cirrhosis</th>
<th>With compensated cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment Naive</strong></td>
<td>Daily Zepatier <strong>Class I, Level A</strong></td>
<td>Daily Harvoni <strong>Class I, Level A</strong></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>HCV RNA &lt;6,000,000 IU/mL (8 weeks)*</td>
<td>HCV RNA &gt;6,000,000 IU/mL (12 weeks)</td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>With compensated cirrhosis</strong></td>
<td>8-12 weeks</td>
<td>12 weeks</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

### Prior PEG-IFN + RBV failed

<table>
<thead>
<tr>
<th>Treatment Experienced</th>
<th>Without cirrhosis</th>
<th>With compensated cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>Daily Zepatier <strong>Class I, Level A</strong></td>
<td>Daily Harvoni <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td><strong>With compensated cirrhosis</strong></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
<td>Daily Zepatier <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td><strong>Prior NS3 PI (telaprevir, boceprevir, or simeprevir) + PEG-INF/RBV regimen failed</strong></td>
<td>Daily Harvoni <strong>Class I, Level A</strong></td>
<td>Daily Harvoni + weight based ribavirin <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td><strong>With compensated cirrhosis</strong></td>
<td>Daily Harvoni + weight-based ribavirin <strong>Class Ia, Level B</strong></td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>Prior sofosbuvir plus RBV +/- PEG-INF regimen failed</strong></td>
<td>Daily Harvoni + weight-based ribavirin <strong>Class Ia, Level B</strong></td>
<td>24 weeks</td>
</tr>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>12 weeks</td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>With compensated cirrhosis</strong></td>
<td>12 weeks</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

### Prior sofosbuvir regimen failed

<table>
<thead>
<tr>
<th>Treatment Experienced</th>
<th>Without cirrhosis</th>
<th>With compensated cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>Daily Harvoni <strong>Class I, Level A</strong></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td><strong>With compensated cirrhosis</strong></td>
<td>Daily Harvoni + weight-based ribavirin <strong>Class I, Level A</strong></td>
<td>Daily Epclusa <strong>Class I, Level A</strong></td>
</tr>
<tr>
<td><strong>Prior PEG-IFN/RBV regimen failed</strong></td>
<td>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. <strong>Class IIb, Level C</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Prior NS5A inhibitor regimen failed*

<table>
<thead>
<tr>
<th>Treatment Experienced</th>
<th>Without cirrhosis</th>
<th>With compensated cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>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. <strong>Class IIb, Level C</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Prior NS3 PI (telaprevir, boceprevir, or simeprevir) + PEG-INF/RBV regimen failed

<table>
<thead>
<tr>
<th>Treatment Experienced</th>
<th>Without cirrhosis</th>
<th>With compensated cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>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. <strong>Class IIb, Level C</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Prior sofosbuvir regimen failed

<table>
<thead>
<tr>
<th>Treatment Experienced</th>
<th>Without cirrhosis</th>
<th>With compensated cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>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. <strong>Class IIb, Level C</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Prior PEG-IFN/RBV regimen failed

<table>
<thead>
<tr>
<th>Treatment Experienced</th>
<th>Without cirrhosis</th>
<th>With compensated cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>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. <strong>Class IIb, Level C</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Prior sofosbuvir regimen failed

<table>
<thead>
<tr>
<th>Treatment Experienced</th>
<th>Without cirrhosis</th>
<th>With compensated cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Without cirrhosis</strong></td>
<td>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. <strong>Class IIb, Level C</strong></td>
<td></td>
</tr>
</tbody>
</table>

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*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.

# NSSA 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.
<table>
<thead>
<tr>
<th>Genotype 2</th>
<th>Treatment naïve</th>
<th>Without cirrhosis</th>
<th>Daily Epclusa Class I, Level A</th>
<th>12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Experienced</td>
<td>With compensated cirrhosis</td>
<td>Daily Epclusa Class I, Level A</td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td>Prior PEG-IFN + RBV failed</td>
<td>Without cirrhosis</td>
<td>Daily Epclusa Class I, Level A</td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>With compensated cirrhosis</td>
<td>Daily Epclusa Class I, Level A</td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td>Prior sofosbuvir + RBV failed</td>
<td>+/- compensated cirrhosis</td>
<td>Daily Epclusa + weight based ribavirin Class Ia, Level C</td>
<td>12 weeks</td>
<td></td>
</tr>
</tbody>
</table>

Genotype 3

| Treatment naïve | Without cirrhosis | Daily Sovaldi + Daklinza Class I, Level A | 12 weeks |
| Treatment Experienced | With compensated cirrhosis | Daily Epclusa Class I, Level A | 12 weeks |

Prior PEG-IFN + RBV failed

| Without cirrhosis | Daily Sovaldi + Daklinza Class I, Level A | 12 weeks |
| With compensated cirrhosis | Daily Epclusa Class I, Level A | 12 weeks |
| +/- compensated cirrhosis | Daily Epclusa + weight based ribavirin Class Ia, Level C | 12 weeks |

Genotype 4

| Treatment naïve | +/- compensated cirrhosis | Daily Epclusa Class I, Level A | 12 weeks |
| Treatment Experienced | Without cirrhosis | Daily Zepatier Class Ia, Level B | 12 weeks |
| | With compensated cirrhosis | Daily Harvoni Class Ia, Level B | 12 weeks |

Prior PEG-IFN + RBV failed

| Without cirrhosis | Daily Epclusa Class I, Level A | 12 weeks |
| With compensated cirrhosis | Daily Harvoni Class Ia, Level B | 12 weeks |
| +/- compensated cirrhosis | Daily Harvoni + weight based ribavirin (if ribavirin eligible) Class Ia, Level B | 12 weeks |

Genotype 5

| Treatment naïve | +/- compensated cirrhosis | Daily Epclusa Class I, Level A | 12 weeks |
| Treatment Experienced | Prior PEG-IFN + RBV failed | Daily Harvoni Class Ia, Level B | 12 weeks |

Genotype 6

| Treatment naïve | +/- compensated cirrhosis | Daily Epclusa Class I, Level A | 12 weeks |
| Treatment Experienced | Prior PEG-IFN + RBV failed | Daily Harvoni Class Ia, Level 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. **Class I, Level A** |
| Daklinza requires dose adjustment with ritonavir-boosted atazanavir (a decrease to 30mg daily) and efavirenz or etravirine (an increase to 90mg daily). **Class IIa, Level 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. **Class IIa, Level 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. **Class IIa, Level 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. **Class IIa, Level 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. **Class IIa, Level C** |
| For combinations expected to increase tenofovir levels, baseline and ongoing assessment for tenofovir nephrotoxicity is recommended. **Class IIa, Level C** |
| 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. **Class IIa, Level C** |

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. **Class I, Level A** |
| For patients with genotype 1a, 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. **Class IIa, Level 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. **Class IIb, Level 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. **Class IIb, Level 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. **Class IIb, Level 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 naive 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**

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 ≥ 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 ≥ 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:
  o **Topical agents:** emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene
  o **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.

**References**
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 >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 >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 that feels 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; TNFα = tumor necrosis factor α.

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 (<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; TNFα = tumor necrosis factor α.

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512
Increlex® (mecasermin) Criteria:

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

a) 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 ≤ -3.0
   AND
   ii. Basal IGF-1 standard deviation score ≤ -3.0
   AND
   iii. Normal or elevated growth hormone level
   AND
b) Member is ≥ 2 years old (safety and efficacy has not been established in patients < 2 years)
   AND
c) Member has documentation of open epiphyses
   AND
d) 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.
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 >=190mg/dl or 40-75 years of age with diabetes and ASCVD risk >=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 >=20mg
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 >=20mg
   d. pravastatin >=40mg
   e. lovastatin 40mg
   f. fluvastatin XL 80mg
   g. fluvastatin 40mg BID
   h. pitavastatin >=2mg
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 statin trials 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 >= 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) 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 ≥ 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 ≥ 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

Last reviewed/updated: 8/3/15
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 ≥ 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
- 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) 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 ≥ 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


Last reviewed/updated: 4/6/15
Korlym® (mifepristone)  
Prior Authorization Criteria  
Drug Protocol Management

Korlym® 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®?
- 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®
- The member is new to NHP and has been stabilized on Korlym® 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® (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
  Last reviewed/updated: 11/10/14
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**

Kynamro® (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®?
- 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 ≥ 18 years of age AND
- Patient is new to NHP and has already been started and stabilized on Kynamro® OR
- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND
- Patient is ≥ 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®

References


Last reviewed/updated: 1/12/15
Lemtrada® (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®?

- 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® for the approvable indication
  **OR**
- Patient has a diagnosis of a relapsing form of multiple sclerosis (MS) AND
- Patient is ≥ 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®, Avonex®, Betaseron®, Extavia®, Plegridy®, etc.)*
  - glatiramer acetate (Copaxone®)*
  - dimethyl fumarate (Tecfidera®)
  - teriflunomide (Aubagio®)
  - fingolimod (Gilenya®)

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

References

• Paty DW, Li DXB, MS/MRI Study Group, IFNB MS Study Group. Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. 11. MRI analysis results of a multicenter, randomized, double-blind, placebo-controlled trial. Neurology. 1993;43:662-667.
• REBIF prescribing information. EMD Serono. Rockland, MA. April 2014.
Omega-3-acid ethyl esters (Lovaza®) & Vascepa® (icosapent ethyl)
Prior Authorization Criteria
Drug Protocol Management

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 (≥ 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:
  o Fibric acid derivatives (e.g. fenofibrate, gemfibrozil, etc.)
  o Long-acting niacin agents (e.g. niacin ER, Niaspan®, Simcor®, Advicor®, etc.)
  o HMG-CoA reductase inhibitors (aka “Statins”: simvastatin, atorvastatin, rosvuastatin, etc.)

Approval 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:
  o Fibric acid derivatives (e.g. fenofibrate, gemfibrozil, etc.)
  o Long-acting niacin agents (e.g. niacin ER, Niaspan®, Simcor®, Advicor®, etc.)
  o HMG-CoA reductase inhibitors (aka “Statins”: simvastatin, atorvastatin, rosvuastatin, etc.)

AND

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

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

References
  Last reviewed/updated: 8/3/15
Makena® (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®?

- 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


Last reviewed/updated: 7/1/14
Neupro™ (rotigotine transdermal system)  
Prior Authorization Criteria  
Drug Protocol Management

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  

Last reviewed/updated: 1/12/15
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

  Last reviewed/update: 1/12/15
Nuedexța® (dextromethorphan hydrobromide/quinidine sulfate)

- Quantity Limit: 60 capsules/30 days

How do I obtain a prior authorization for Nuedexța®?
- 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 Nuedexța®, 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

Last reviewed/updated: 1/12/15
Elquis® (apixaban), Pradaxa® (dabigatran), Xarelto® (rivaroxaban)

- Quantity Limit
  - Elquis® (apixaban): 60 tablets/30 days
  - Pradaxa® (dabigatran): 60 capsules/30 days
  - Xarelto® (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 Elquis® (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
  - 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® (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
  - 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® (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
  - Dosage prescribed is within the FDA-approved dosage range for the given indication.
• 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

Last reviewed/updated: 12/10/14
Oravig® (miconazole) buccal tablets
Prior Authorization Criteria Drug
Protocol Management

Oravig® (miconazole) 50 mg buccal tablets

How do I obtain a prior authorization for Oravig®?
• 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 ≥ 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
Appendix 1

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512
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 (≤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; TNFα = tumor necrosis factor α.

Source: Arthritis & Rheumatism. 2013;65(10):2499-2512
Otezla® (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®?
- 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® for an approveable indication

OR
- Patient is ≥ 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)*† 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 ≥ 18 years if age AND
- Patient has a diagnosis of moderate to severe chronic plaque psoriasis affecting ≥ 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:
  o **Topical agents**: emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene
  o **Systemic agents**: methotrexate, sulfasalazine, cyclosporine, tacrolimus, acitretin, mycophenolate mofetil, azathioprine, hydroxyurea, etc.
  o **Phototherapy**: ultraviolet A and topical psoralen (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 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


Last reviewed/updated: 4/6/15
Oxcellar XR™ (oxcarbazepine extended release) Prior Authorization Criteria
Drug Protocol Management

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

Prolia® (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®?
- 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® 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) **AND**
- Patient will continue to receive daily calcium and vitamin D therapies

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

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
- Institute for Clinical Systems Improvement (ICSI). Healthcare Guideline: Diagnosis and Treatment of Osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 July. Available at: https://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_musculoskeletal_guidelines/osteo/p

Last reviewed/updated: 4/6/15
Promacta® (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®?
- 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 immune thrombocytopenia purpura (ITP)
- Thrombocytopenia in patients with chronic hepatitis C to allow for initiation and maintenance of interferon-based therapy
- Severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy

Approval Criteria
- Patient is new to NHP and has been stabilized on Promacta® for an approvable indication OR
- Patient has a diagnosis of chronic ITP AND
- Patient has had a documented treatment failure with corticosteroids or immunoglobulins OR is status-post splenectomy

- Patient has a diagnosis of thrombocytopenia and chronic hepatitis C AND
- Patient will initiate interferon-based therapy and current platelet count is ≤ 75,000 cells/mm³ OR
- Patient has already initiated and is stable on Promacta® therapy and the current platelet count supports continued use of Promacta® (per prescribing information) AND
- Patient requires continued antiviral therapy for the management of chronic hepatitis C OR
- Patient has a diagnosis of severe aplastic anemia AND
- Patient has had a documented inadequate response with immunosuppressive therapy (e.g., anti-thymocyte globulin, cyclosporine, steroids, etc.)

Initial approvals may be issued for up to 3 months for all indications except severe aplastic anemia; initial approvals for aplastic anemia may be issued for up to 4 months.

Reauthorization Criteria
Chronic immune thrombocytopenia purpura (ITP)
• Improvement per physician assessment/evaluation of overall disease activity, including improvement in platelet counts.

**Thrombocytopenia in chronic hepatitis C**

• Improvement in platelet counts (levels not to exceed 400 x 10^9/L).

**Severe aplastic anemia**

• Improvement per physician assessment/evaluation of overall disease activity, including improvement in platelet counts to achieve the target ≥ 50 x 10^9/L as necessary.

Reauthorizations may be granted for up to 1 year for all indications except thrombocytopenia in chronic hepatitis C; reauthorizations for thrombocytopenia in chronic hepatitis C may be granted for up to 3 months.

**References**

• Aplastic Anemia [webpage on the internet]. Aplastic anemia & MDS: International Foundation. 2014. Available at: http://www.aamds.org/about/aplastic-anemia

Last reviewed/updated: 8/4/15
Modafinil (Provigil®) and Nuvigil® (armodafinil)
Prior Authorization Criteria
Drug Protocol Management

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

- Nuvigil [package insert]. Frazer (PA); Cephalon Inc; 2013 Jun.
Qudexy™ XR (topiramate extended release)
Prior Authorization Criteria
Drug Protocol Management

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

Last reviewed/approved: 11/3/14
Ranexa® (ranolazine) Prior Authorization criteria Drug Protocol Management

Ranexa® (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®?
- 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®, 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®:
  - 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.)
  - 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.

† 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.

Last reviewed/updated: 11/10/14
Tamiflu® (oseltamivir) and Relenza® (zanamivir)
Prior Authorization Criteria
Drug Protocol Management

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

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

**How do I obtain a prior authorization for Tamiflu® or Relenza®?**

- 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 ≥ 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 ≥ 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:
  o Absence of vaccination for the current flu season
  o Insufficient time to develop immunity between vaccination and likely exposure
  o Presence of an active outbreak of influenza among institutionalized residents
  o Circulating influenza viruses strains are different than the strains used to develop the vaccine

AND

• The patients is ≥ 1 year of age (for Tamiflu®) or ≥ 5 years of age (for Relenza®)

Coverage criteria May 1st-September 30th:

• The diagnosis is treatment of influenza

AND

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

AND

• The patient is ≥ 2 weeks of age (for Tamiflu®) or ≥ 7 years (for Relenza®)

OR

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

AND

• The patient has at least one of the following risk factors:
  o Age of ≥ 50 years
  o Age between 6 and 59 months
  o Healthcare worker
  o Chronic cardiovascular or pulmonary disease (e.g., including asthma, but not hypertension)
  o Chronic metabolic or endocrine disease (e.g., diabetes, etc.)
  o Morbid obesity (BMI of ≥ 40)
  o Renal failure or hepatic disorder
  o Hematological disorder or a hemoglobinopathy (e.g., sickle cell anemia, thalassemia, etc.)
  o Immunosuppression (e.g., immunosuppression secondary to corticosteroid therapy, immunosuppressive therapy, chemotherapy, HIV/AIDS, etc.)
  o Cancer
  o Current pregnancy or planned pregnancy during flu season
  o American Indian, Alaska native, or resident of a nursing home/long-term care facility/chronic care facility
  o Unvaccinated infant between 12 and 24 months of age
  o Child or adolescent (ages 6 months to 18 years) who is receiving long-term aspirin therapy
  o 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:
  o Absence of vaccination for the current flu season
  o Insufficient time to develop immunity between vaccination and likely exposure
  o Presence of an active outbreak of influenza among institutionalized residents
  o Circulating influenza viruses strains are different than the strains used to develop the vaccine

AND

• The patients is ≥ 1 year of age (for Tamiflu®) or ≥ 5 years of age (for Relenza®)
Additional Information

- If the patient is a nursing home resident OR has underlying airway disease (e.g., asthma or COPD), Relenza® 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

Relistor® (methylnaltrexone)
Prior Authorization Criteria
Drug Protocol Management

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

Last reviewed/updated: 4/6/15
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 ≥ 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
  o Improvement per physician and member assessment of overall disease activity/severity

Plaque psoriasis
  o 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


Last reviewed/updated: 4/6/15
Restasis® (cyclosporine ophthalmic emulsion)
Prior Authorization criteria
Drug Protocol Management

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
• Lee HS, Jang JY, Lee SH, Im SK, Yoon KC. Clinical effectiveness of topical cyclosporine a 0.05% after laser epithelial keratomileusis. Cornea. 2013;32(7):e150-5.

Last reviewed/updated 11/10/2014
Adcirca® (tadalafil) tablets, Revatio® (sildenafil) oral suspension, and sildenafil (Revatio®) tablets
Prior Authorization Criteria
Drug Protocol Management

Adcirca® (tadalafil) tablets, Revatio® (sildenafil) oral solution, and sildenafil (Revatio®) tablets are specialty products; dispensing is available from NHP’s preferred specialty pharmacy provider CVS/caremark. The following quantity limits apply:
- **Adcirca® (tadalafil) tablets:** 60 tablets per 30 days
- **Revatio® (sildenafil) oral solution:** 224 mL (2 bottles) per 30 days
- **Sildenafil (Revatio®) tablets:** 90 tablets per 30 days

How do I obtain a prior authorization for Adcirca®, Revatio® oral solution, or sildenafil tablets?
- 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**
- Pulmonary arterial hypertension (WHO group I) to improve exercise ability

**Approval Criteria**
- Patient has a diagnosis of pulmonary hypertension **AND**
- The requested dosing regimen does not exceed the quantity limits specified above **AND**
- Patient is not using a guanylate cyclase inhibitor (e.g., riociguat [Adempas®]) and is also not using nitrates, either regularly or intermittently

Initial approvals and reauthorizations may be issued for up to 12 months.

**References**

Last reviewed/updated: 8/3/15
Savella® (milnacipran HCL)
Prior Authorization Criteria
Drug Protocol Management

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

Last reviewed/updated: 1/12/15
Short-Acting Fentanyl Products
Prior Authorization Criteria
Drug Protocol Management

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®, Susbys®
- 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


Last reviewed/updated: 8/3/15
Simponi® and Simponi® 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®; for Simponi® 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® or Simponi® 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® Aria:
- Moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate
- 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® Aria
- Patient is new to NHP and has been stabilized on Simponi® Aria for an approvable indication OR
- Patient is ≥ 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®
- Patient is new to NHP and has been stabilized on Simponi® for an approvable indication OR
- Patient is ≥ 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 ≥ 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† OR
- Patient is ≥ 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:
  o Inducing and maintaining clinical response
  o Improving endoscopic mucosa appearance during induction
  o Inducing clinical remission
  o 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® and Simponi® Aria may be issued for up to 6 months∞.

∞ Simponi® 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
Solaraze® (diclofenac sodium) 3% topical gel

Prior Authorization Criteria
Drug Protocol Management

Solaraze® (diclofenac sodium) 3% topical gel

How do I obtain a prior authorization for Solaraze®?

- 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®, etc.), topical imiquimod (Aldara®, Zyclara®) AND Picato® gel
  OR
- The member is pregnant

<table>
<thead>
<tr>
<th>Medications</th>
<th>First-Line Drugs</th>
<th>Second-Line Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>imiquimod (Aldara®, Zyclara®) fluorouracil (Efudex®, 5-FU, etc.) Picato® gel</td>
<td>Solaraze® (diclofenac)</td>
</tr>
</tbody>
</table>

Last reviewed/updated: 6/3/13
Stelara® (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®?
- 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® for an approvable indication
  OR
- Patient is ≥ 18 years if age AND
- Patient has a diagnosis of moderate to severe plaque psoriasis affecting ≥ 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:
  o Topical agents: emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene
  o Systemic agents: methotrexate, sulfasalazine, cyclosporine, tacrolimus, acitretin, mycophenolate mofetil, azathioprine, hydroxyurea, etc.
  o Phototherapy: ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB), etc.
  OR
- Patient is ≥ 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


Last reviewed/updated: 4/6/15
buprenorphine (Subutex®)
Prior Authorization criteria
Drug Protocol Management

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

Last reviewed/updated: 6/25/12
How do I obtain a prior authorization for Symlin®?

- 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.
  - The patient has demonstrated an expected reduction in HbA1c since starting the therapy.
  - 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
  - The patient is currently receiving optimal mealtime insulin therapy.
  - The patient has experienced an inadequate treatment response to insulin
  - 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 an 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.5 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.5 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


Last reviewed/updated: 4/25/16
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:

<table>
<thead>
<tr>
<th>Group</th>
<th>Younger than 12 months of age at start of RSV season</th>
<th>Second year of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm infants without CLD or CHD</td>
<td>Indicated if born before 29 weeks, 0 days. Infants born during the RSV season will need fewer than five monthly doses.</td>
<td>Not indicated.</td>
</tr>
<tr>
<td>Preterm infants with CLD</td>
<td>Indicated if born before 32 weeks, 0 days and require &gt;21% oxygen for at least the first 28 days after birth.</td>
<td>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.</td>
</tr>
</tbody>
</table>

(cont.)
<table>
<thead>
<tr>
<th>Group</th>
<th>Younger than 12 months of age at start of RSV season</th>
<th>Second year of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm infants with CHD*</td>
<td>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.</td>
<td>Not indicated.</td>
</tr>
<tr>
<td>Infants who receive cardiac transplant during RSV season</td>
<td>Indicated.</td>
<td>Indicated.</td>
</tr>
<tr>
<td>Infants with anatomic pulmonary abnormalities or neuromuscular disorders that impair the ability to clear respiratory secretions from the upper airway because of ineffective cough</td>
<td>Indicated.</td>
<td>Not indicated.</td>
</tr>
<tr>
<td>Infants who are profoundly immunocompromised during RSV season</td>
<td>Indicated.</td>
<td>Indicated.</td>
</tr>
<tr>
<td>Infants with CF</td>
<td>CF + CLD and/or nutritional compromise.</td>
<td>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 10th percentile.</td>
</tr>
</tbody>
</table>

*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

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

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
    • Q
    • R
  • 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

Last reviewed/updated: 11/10/14
Trokendi XR™ (topiramate extended release)
Prior Authorization Criteria
Drug Protocol Management

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

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.
  - The patient has a medical need for testing more frequently than 8 times per day.

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
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

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-α), 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


Last reviewed/updated: 8/3/15
Uloric® (febuxostat) Prior Authorization Criteria Drug Protocol Management

Uloric® (febuxostat)
- Quantity Limit: 30 tablets/30 days

How do I obtain a prior authorization for Uloric®?
- 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 ≥ 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

Last reviewed/updated: 1/12/15
Calcitriol (Vectical®) Prior Authorization Criteria Drug Protocol Management

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 ≥ 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† AND
- Patient has demonstrated inadequate response, adverse reaction or contraindication to calcipotriene cream (Dovonex®)

† 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
Xartemis™ XR (oxycodeone 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 (Ultrace®)
  - 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


Last reviewed/updated: 4/6/15
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 ≥ 500 cells/mm³
  - Absolute neutrophil count (ANC) > 500 cells/mm³
  - Hemoglobin level ≥ 8.0 g/dL, with no more than a 2 g/dL since initiation of Xeljanz®

Reauthorizations may be granted for up to 12 months.

References


Last reviewed/updated: 4/6/15
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
  • Tetrabenazine (Xenazine) for Huntington’s chorea. The Medical Letter. 2009;51(1304):7-8.

Last reviewed/updated: 8/3/15
Xgeva® (denosumab) Prior
Authorization criteria Drug
Protocol Management

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 ≥ 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

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:

<table>
<thead>
<tr>
<th></th>
<th>Beclomethasone QVAR®</th>
<th>Budesonide Pulmicort®</th>
<th>Flunisolide AeroBID®</th>
<th>Fluticasone Flovent®</th>
<th>Mometasone Asmanex®</th>
<th>Triamcinolone Azmacort®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>&gt;480 mcg/d</td>
<td>&gt;1200mcg/d</td>
<td>&gt;2000mcg/d</td>
<td>&gt;660mcg/d</td>
<td>&gt;400mcg/d</td>
<td>&gt;1500mcg/d</td>
</tr>
</tbody>
</table>

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® (>500/50 twice daily), or
high dose Advair HFA® (>115/21, 2 puffs twice daily), or
high dose Symbicort® (>160/4.5, 2 puffs twice daily), or
high dose Dulera® (>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:
a. daily use of bronchodilator therapy, or
b. an asthma hospitalization within the past 12 months, or
c. > 2 systemic steroid bursts within past 3 months.

Appropriate Dosing:

<table>
<thead>
<tr>
<th>ADMINISTRATION EVERY 4 WEEKS (Milligrams of omalizumab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-treatment Serum IgE (IU/mL)</td>
</tr>
<tr>
<td>30-60</td>
</tr>
<tr>
<td>30-100</td>
</tr>
<tr>
<td>101-200</td>
</tr>
<tr>
<td>201-300</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADMINISTRATION EVERY 2 WEEKS (Milligrams of omalizumab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-treatment Serum IgE (IU/mL)</td>
</tr>
<tr>
<td>101-200</td>
</tr>
<tr>
<td>201-300</td>
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<tr>
<td>301-400</td>
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<td>401-500</td>
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<td>501-600</td>
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<td>601-700</td>
</tr>
</tbody>
</table>

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.

Last reviewed/updated: 1/21/14
Xopenex® (levalbuterol)
Prior Authorization Criteria
Drug Protocol Management

<table>
<thead>
<tr>
<th>Products Included in the Xopenex® Prior Authorization Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levalbuterol (Xopenex®) concentrated nebulizer solution (1.25mg/0.5ml)</td>
</tr>
<tr>
<td>Levalbuterol (Xopenex®) nebulizer solution (0.31mg/3mL, 0.63mg/3mL, &amp; 1.25mg/3mL)</td>
</tr>
<tr>
<td>Xopenex® (levalbuterol) HFA inhalation aerosol (metered dose inhaler)</td>
</tr>
</tbody>
</table>

How do I obtain a prior authorization for levalbuterol (Xopenex®)?

- 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®, Accuneb®, etc.
- albuterol metered-dose inhaler (MDI) or dry powder inhaler: albuterol, Proventil® HFA, Ventolin® HFA, Combivent®, etc.

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

References


Last reviewed/updated: 11/10/14
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 ≥ 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-opioid therapies (acetaminophen, ibuprofen, tramadol, topical remedies, etc.) AND
• Patient’s severe pain has remained uncontrolled despite adequate treatment with opioid therapies, including all of the following:
  o morphine extended-release tablets or capsules (MS Contin®, Avinza®, Kadian®, etc.)
  o fentanyl transdermal (Duragesic®)
  o oxycodone extended-release tablets (OxyContin®)
  o hydromorphone extended-release tablets (Exalgo® ER)

Approvals will be for a duration of 12 months.

References


Last reviewed/updated: 4/6/15
Linezolid (Zyvox®) tablets & Zyvox® (linezolid) oral suspension
Prior Authorization Criteria
Drug Protocol Management

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

Last reviewed/updated: 8/3/15
Zolinza® (vorinostat) Capsules
Prior Authorization Criteria
Drug Protocol Management

How to 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

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

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

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