Dupixent (dupilumab)

**Line(s) of Business:**
HMO; PPO; QUEST Integration

**Effective Date:**
TBD

**POLICY**

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

**FDA-Approved Indications**
Dupixent is indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.

**B. REQUIRED DOCUMENTATION**
The following information is necessary to initiate the prior authorization review:
1. For new starts on therapy, documentation in the chart or medical record of:
   a. Pre-treatment Investigator’s Global Assessment (IGA) score, Eczema Area and Severity Index (EASI) score and percent of body surface area (BSA) involvement
   b. Documentation supporting an inadequate response to BOTH a medium to very high potency topical corticosteroid AND topical tacrolimus (Protopic)
2. For continuation of therapy, documentation in the chart or medical record supporting a response to Dupixent therapy such as a decrease in severity or body surface area involvement when compared to baseline must be submitted

**C. PRESCRIBER RESTRICTION**
Dupixent must be prescribed by or in consultation with a dermatologist, allergist or immunologist.

**D. CRITERIA FOR APPROVAL**
Initial authorization of 4 months may be granted when the following criteria are met:
1. Age 18 years or older
2. Atopic dermatitis is moderate to severe as defined by all of the following:
   a. Investigator’s Global Assessment (IGA) score ≥3 in the overall assessment of AD lesions, and
   b. Eczema Area and Severity Index (EASI) score ≥16, and
   c. Minimum body surface area (BSA) involvement of ≥10%
3. Documented inadequate response to BOTH of the following topical therapies within the past 6 months:
a. Medium, high or very high potency topical corticosteroid (refer to Appendix in Section J for examples) for at least 4 weeks or the maximum duration recommended by the prescribing information, AND
b. Topical tacrolimus ointment 0.1% (Protopic) for at least 6 weeks

E. CONTINUATION OF THERAPY
All members, including new members, must meet all initial authorization criteria in Section D.
Authorization of 6 months may be granted to members requesting authorization for continuation of therapy if Dupixent was previously authorized HMSA and a clinical response was achieved and/or maintained as defined by ANY of the following:
1. Decrease in IGA score from baseline
2. Decrease in EASI score from baseline
3. Decrease in BSA involvement from baseline

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

G. ADMINISTRATIVE GUIDELINES
Prior authorization is required. Please refer to the HMSA medical policy web site for the fax form.

H. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES

**APPENDIX**

Examples of Medium, High and Very High Potency Topical Corticosteroids

<table>
<thead>
<tr>
<th>Class</th>
<th>Drug</th>
<th>Dosage form(s)</th>
<th>Strength (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Very high potency</strong></td>
<td>Augmented betamethasone dipropionate</td>
<td>Ointment</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Clobetasol propionate</td>
<td>Cream, foam, ointment</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Diflorasone diacetate</td>
<td>Ointment</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Halobetasol propionate</td>
<td>Cream, ointment</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>High potency</strong></td>
<td>Amcinonide</td>
<td>Cream, lotion, ointment</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Augmented betamethasone dipropionate</td>
<td>Cream</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Betamethasone dipropionate</td>
<td>Cream, foam, ointment, solution</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Desoximetasone</td>
<td>Cream, ointment</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>Desoximetasone</td>
<td>Gel</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Diflorasone diacetate</td>
<td>Cream</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Fluocinonide</td>
<td>Cream, gel, ointment, solution</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Halcinonide</td>
<td>Cream, ointment</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Mometasone furoate</td>
<td>Ointment</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Triamcinolone acetonide</td>
<td>Cream, ointment</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Medium potency</strong></td>
<td>Betamethasone valerate</td>
<td>Cream, foam, lotion, ointment</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Clocortolone pivalate</td>
<td>Cream</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Desoximetasone</td>
<td>Cream</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Fluocinolone acetonide</td>
<td>Cream, ointment</td>
<td>0.025</td>
</tr>
<tr>
<td></td>
<td>Flurandrenolide</td>
<td>Cream, ointment</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Fluticasone propionate</td>
<td>Cream</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Fluticasone propionate</td>
<td>Ointment</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>Mometasone furoate</td>
<td>Cream</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Triamcinolone acetonide</td>
<td>Cream, ointment</td>
<td>0.1</td>
</tr>
</tbody>
</table>
Body Surface Area
To determine extent, the sites affected by eczema are shaded on a drawing of a body. The rule of 9 is used to calculate the affected area as a percentage of the whole body.

- Head and neck 9%
- Upper limbs 9% each
- Lower limbs 18% each
- Anterior trunk 18%
- Back 18%
- 1% for genitals.

http://www.dermnetnz.org/topics/easi-score/
Eczema Area and Severity Index (EASI) Score

Body Regions
There are four body regions:
- Head and neck
- Trunk (including genital area)
- Upper limbs
- Lower limbs (including buttocks)

Area Score
Area score is recorded for each of the four regions of the body. The area score is the percentage of skin affected by eczema.

<table>
<thead>
<tr>
<th>Area score</th>
<th>Percentage of skin affected by eczema in each region</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0: no eczema in this region</td>
</tr>
<tr>
<td>1</td>
<td>1–9%</td>
</tr>
<tr>
<td>2</td>
<td>10–29%</td>
</tr>
<tr>
<td>3</td>
<td>30–49%</td>
</tr>
<tr>
<td>4</td>
<td>50–69%</td>
</tr>
<tr>
<td>5</td>
<td>70–89%</td>
</tr>
<tr>
<td>6</td>
<td>90–100%: the entire region is affected by eczema</td>
</tr>
</tbody>
</table>

Severity Score
Severity score is recorded for each of the four regions of the body. The severity score is the sum of the intensity scores for four signs. The four signs are:
1. Redness (erythema, inflammation)
2. Thickness (induration, papulation, swelling—acute eczema)
3. Scratching (excoriation)
4. Lichenification (lined skin, prurigo nodules—chronic eczema).

The average intensity of each sign in each body region is assessed as: none (0), mild (1), moderate (2) and severe (3).

<table>
<thead>
<tr>
<th>Score</th>
<th>Intensity of redness, thickness/swelling, scratching, lichenification</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None, absent</td>
</tr>
<tr>
<td>1</td>
<td>Mild</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
</tr>
<tr>
<td>3</td>
<td>Severe</td>
</tr>
</tbody>
</table>
Half scores are allowed. It may be difficult to assess redness in dark skin. If in doubt, increase the average redness score by one level. The 16 images below have been chosen as typical examples of different intensities of each sign.

<table>
<thead>
<tr>
<th>Four signs of eczema used to calculate EASI severity score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intensity</strong></td>
</tr>
<tr>
<td>Redness</td>
</tr>
<tr>
<td>Thickness/induration</td>
</tr>
<tr>
<td>Scratching</td>
</tr>
<tr>
<td>Lichenification/prurigo</td>
</tr>
</tbody>
</table>

**Calculations**
For each region, record the intensity for each of four signs and calculate the severity score.
- Severity score = redness intensity + thickness intensity + scratching intensity + lichenification intensity

For each region, multiple the severity score by the area score and by a multiplier. The multiplier is different for each body site.
- Head and neck: severity score x area score x 0.1 (in children 0–7 years, x 0.2)
- Trunk: severity score x area score x 0.3
- Upper limbs: severity score x area score x 0.2
- Lower limbs: severity score x area score x 0.4 (in children 0–7 years, x 0.3)

Add up the total scores for each region to determine the final EASI score. The minimum EASI score is 0 and the maximum EASI score is 72.

**Recording the EASI score**

<table>
<thead>
<tr>
<th>Body region</th>
<th>Redness</th>
<th>Thickness</th>
<th>Scratching</th>
<th>Lichenification</th>
<th>Severity score</th>
<th>Area score</th>
<th>Multiplier</th>
<th>Region score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head/neck</td>
<td>_______</td>
<td>+ _______</td>
<td>+ _______</td>
<td>+ _______</td>
<td>= _______</td>
<td>X _______</td>
<td>X 0.1 (If ≤7 yrs, X 0.2)</td>
<td>= _______</td>
</tr>
<tr>
<td>Trunk</td>
<td>_______</td>
<td>+ _______</td>
<td>+ _______</td>
<td>+ _______</td>
<td>= _______</td>
<td>X _______</td>
<td>X 0.3</td>
<td>= _______</td>
</tr>
<tr>
<td>Upper limbs</td>
<td>_______</td>
<td>+ _______</td>
<td>+ _______</td>
<td>+ _______</td>
<td>= _______</td>
<td>X _______</td>
<td>X 0.2</td>
<td>= _______</td>
</tr>
<tr>
<td>Lower limbs</td>
<td>_______</td>
<td>+ _______</td>
<td>+ _______</td>
<td>+ _______</td>
<td>= _______</td>
<td>X _______</td>
<td>X 0.4 (If ≤7 yrs, X 0.3)</td>
<td>= _______</td>
</tr>
</tbody>
</table>

The final EASI score: add up the 4 region scores

= _______ (0-72)

[http://www.dermnetnz.org/topics/easi-score/](http://www.dermnetnz.org/topics/easi-score/)

**Investigator Global Assessment Scoring System (IGA)**

<table>
<thead>
<tr>
<th>Score</th>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Clear</td>
<td>No inflammatory signs of atopic dermatitis</td>
</tr>
<tr>
<td>1</td>
<td>Almost Clear</td>
<td>Just perceptible erythema and just perceptible papulation induration</td>
</tr>
<tr>
<td>2</td>
<td>Mild</td>
<td>Mild erythema and mild papulation induration. No oozing or crusting.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Moderate erythema and moderate papulation induration. Oozing or crusting may be present.</td>
</tr>
<tr>
<td>4</td>
<td>Severe</td>
<td>Severe erythema and severe papulation induration. Oozing or crusting is present.</td>
</tr>
</tbody>
</table>