I. Description

Biological therapeutics/biopharmaceuticals (biologic agents) are biology-based therapeutic agents that structurally mimic compounds found in the body. These include recombinant proteins, monoclonal and polyclonal antibodies, peptides, antisense oligonucleotides, therapeutic genes and certain therapeutic vaccines.

II. Criteria/Guidelines

A. Biological agents for the treatment of plaque psoriasis are covered (subject to Administrative Guidelines) when all of the following criteria are met:

1. The use of biological agents must be recommended by a dermatologist.
2. The patient is 18 years of age or older with moderate to severe, chronic plaque psoriasis.
   a. Moderate to severe psoriasis is defined as having 10 percent or more body surface area involvement.
   b. Chronic is defined as a history of psoriasis longer than six months.
   c. Plaque psoriasis is characterized by well-defined patches of red and raised skin
3. The patient has tried methotrexate for at least three months at a therapeutic dose and found it to be ineffective, or the patient exhibited intolerance or allergy, or the use of methotrexate is contraindicated.

   • Ineffective treatment is defined as symptoms and/or signs that are not resolved after completion of treatment at the recommended therapeutic dose and duration. If there is no recommended treatment time, the member must have had a meaningful trial.
   • Intolerance is defined as having a recognized and reproducible or repeated adverse reaction that is clearly associated with taking the medication.
   • Allergy is defined as a state of hypersensitivity produced by exposure to a particular antigen resulting in harmful immunologic reactions on subsequent exposures. The most common symptoms are skin rash or anaphylaxis.
4. Continuation of therapy is covered (subject to Administrative Guidelines) when initial therapy has been approved and there is a decrease in percent of body surface area involvement when compared to baseline.

III. Administrative Guidelines

A. Precertification is required for the initial six months of treatment. The following documentation from the medical record must be submitted:
   1. History of plaque psoriasis for longer than six months
   2. Percent of body surface area involvement
   3. Results of treatments with methotrexate.

B. Precertification is required for continuation of therapy for up to an additional 12 months. Documentation supporting a decrease in percent of body surface area involvement when compared to baseline must be submitted.

C. To precertify, please complete HMSA’s Drug Review Request and mail or fax the form as indicated.

D. Remicade does not require precertification. Refer to the policy for Infliximab (Remicade).

E. For QUEST Integration and FED87 members, effective 01/01/2013 precertification for etanercept and/or adalimumab is required through CVS.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>J1438</td>
<td>Injection, etanercept, 25 mg</td>
</tr>
<tr>
<td>J0135</td>
<td>Injection, adalimumab, 20 mg</td>
</tr>
<tr>
<td>J3357</td>
<td>Injection, ustekinumab, 1 mg</td>
</tr>
</tbody>
</table>

IV. 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 HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

V. References