POLICY Document for Stelara

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA
DISEASE-MODIFYING ANTIRHEUMATIC DRUGS PRODUCTS

PREFERRED PRODUCTS: ENTYVIO, ILUMYA, REMICADE, SIMPONI ARIA, STELARA IV

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the disease-modifying antirheumatic drug (DMARD) products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. For psoriasis, this program applies to all adult members requesting treatment with a targeted product. For all other indications, this program applies to adult members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Disease-modifying antirheumatic drugs for autoimmune conditions

<table>
<thead>
<tr>
<th>Products</th>
<th>Preferred</th>
<th>Targeted</th>
</tr>
</thead>
<tbody>
<tr>
<td>EnTTYvio (vedolizumab)</td>
<td>Ilumya (tildrakizumab-asmn)</td>
<td>Actemra (tocilizumab)</td>
</tr>
<tr>
<td>Ilumya (tildrakizumab-asmn)</td>
<td>RemicaDe (inflxiimab)</td>
<td>Avsola (inflxiimab-axxq)</td>
</tr>
<tr>
<td>RemicaDe (inflxiimab)</td>
<td>Simponi Aria (golimumub, intravenous)</td>
<td>Cimzia (certolizumab pegol)</td>
</tr>
<tr>
<td>Simponi Aria (golimumub, intravenous)</td>
<td>Stelara IV (ustekinumab)*</td>
<td>Inflectra (inflxiimab-dyyb)</td>
</tr>
<tr>
<td>Stelara IV (ustekinumab)*</td>
<td></td>
<td>Orenca (abatacept)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Renflexis (inflxiimab-abda)</td>
</tr>
</tbody>
</table>

*Stelara IV is indicated for a one time induction dose for Crohn’s disease and ulcerative colitis.

II. EXCEPTION CRITERIA

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This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. For Avsola, Inflectra and Renflexis, when member meets both of the following:
   1. Member has a documented intolerable adverse event with the preferred product, Remicade, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
   2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, and Simponi Aria where the product’s indications overlap.

B. For Cimzia, when any of the following criteria are met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer’s patient assistance programs, unless the request is for psoriasis.
   2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, Remicade, and Simponi Aria where the product’s indications overlap.
   3. Member is currently pregnant or breastfeeding.

C. For all other targeted products, when any of the following criteria are met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer’s patient assistance programs.
   2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, Remicade, and Simponi Aria where the product’s indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (Appendix)

III. Appendix: Clinical reasons to avoid TNF inhibitors
   - History of demyelinating disorder
   - History of congestive heart failure
   - History of hepatitis B virus infection
   - Autoantibody formation/lupus-like syndrome
   - Risk of lymphoma

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

STELARA (ustekinumab)

POLICY

I. INDICATIONS

   The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.
1. **FDA-Approved Indications**
2. Moderate to severe plaque psoriasis (PsO)
3. Active psoriatic arthritis (PsA)
4. Moderately to severely active Crohn’s disease (CD)
5. Moderately to severely active ulcerative colitis (UC)

All other indications are considered experimental/investigational and not medically necessary.

II. **CRITERIA FOR INITIAL APPROVAL**

A. **Moderate to severe plaque psoriasis (PsO)**
   - Authorization of 12 months may be granted for members who previously received Otezla or a biologic indicated for the treatment of moderate to severe plaque psoriasis.

B. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:
   1. At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   2. Member meets any of the following criteria:
      i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or a pharmacologic treatment with methotrexate, cyclosporine or acitretin.
      ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (see Appendix A).
      iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy (i.e. at least 10% of the body surface area (BSA) or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected).

B. **Active psoriatic arthritis (PsA)**
   - Authorization of 12 months may be granted for treatment of active psoriatic arthritis.

C. **Moderately to severely active Crohn’s disease (CD)**
   1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of Crohn’s disease.
   2. Authorization of 12 months may be granted for the treatment of moderately to severely active CD in members who had an inadequate response, intolerance or contraindication to at least one conventional therapy option (See Appendix B).

D. **Moderately to severely active ulcerative colitis (UC)**
   1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis.
2. Authorization of 12 months may be granted for the treatment of moderately to severely active UC for members who had an inadequate response, intolerance or contraindication to at least one conventional therapy option (See Appendix C).

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who are using Stelara for an indication outlined in section II and achieve or maintain a positive clinical response with Stelara as evidenced by low disease activity or improvement in signs and symptoms of the condition.

IV. OTHER

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs (e.g., Xeljanz), and repeated yearly for members with risk factors** for TB that are continuing therapy with biologics.

* If the screening testing for TB is positive, there must be documentation of further testing to confirm there is no active disease. Do not administer ustekinumab to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of ustekinumab.

** Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

For all indications: Member cannot use Stelara concomitantly with any other biologic DMARD or targeted synthetic DMARD.

Stelara for intravenous administration is FDA-approved for the treatment of Crohn’s disease and ulcerative colitis and will only be authorized for these conditions.

V. APPENDICES

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.
1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix B: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
   a. Oral budesonide
   b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternatives: oral budesonide, methotrexate intramuscular (IM) or subcutaneous (SC), sulfasalazine
3. Moderate to severe disease – induction of remission:
   a. Prednisone, methylprednisolone intravenously (IV)
   b. Alternatives: methotrexate IM or SC
4. Moderate to severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: methotrexate IM or SC
5. Perianal and fistulizing disease – induction of remission:
   a. Metronidazole ± ciprofloxacin, tacrolimus
6. Perianal and fistulizing disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: methotrexate IM or SC

Appendix C: Examples of conventional therapy options for UC

1. Mild to moderate disease – induction of remission:
   a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
   b. Rectal mesalamine (e.g., Canasa, Rowasa)
   c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)
   d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
   a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
   b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
   a. Prednisone, hydrocortisone IV, methylprednisolone IV
   b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: sulfasalazine
5. Pouchitis: Metronidazole, ciprofloxacin
   a. Alternative: rectal mesalamine
REFERENCES

SECTION 1

SECTION 2
   Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and
    Gastroentrol. 2019;114:384-413.