Ustekinumab

Adjudication Guideline

Rule Category: Pharmaceutical	**Ref: No:** 2023-PH-20	**Version Control:** Version No. V1.0	**Effective Date:** 01st April 2023	**Last Update:** 05/06/23
Approved by: Daman	**Responsible:** Medical Standards & Research	**Related Adjudication Guidelines:** NA		

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1. Abstract

1.1 For Members

Ustekinumab is a drug that reduces the signs and symptoms of active psoriatic arthritis, such as psoriasis and joint swelling. It is also approved for the treatment of plaque psoriasis and moderate to severe, active Crohn's disease. It is a type of drug called a biologic.

1.2 For Medical Professionals

Ustekinumab is a human IgG1κ monoclonal antibody that binds with specificity to the p40 protein subunit used by both the IL-12 and IL-23 cytokines

2. Scope

The scope of this adjudication rule is to highlight the medical indications, and coverage details for ustekinumab as per the policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

1. **Plaque psoriasis** [1,2]: is indicated in adults, children and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies with minimum body surface area involvement of 10%

2. **Psoriatic arthritis (PsA):** is indicated for the treatment of patients 6 years or older with active psoriatic arthritis [1].

3. **Crohn's Disease** [1,2]: is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with lost response to or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies [1]. In Crohn's disease if therapy is interrupted, resumption of treatment with subcutaneous dosing every 8 weeks is safe and effective [2].

4. **Ulcerative colitis** [1,2]**:** is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with lost response to or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies [1]. In Crohn's disease if therapy is interrupted, resumption of treatment with subcutaneous dosing every 8 weeks is safe and effective [2].

Pre-treatment Evaluation for Tuberculosis [1]:
Evaluate patients for tuberculosis infection prior to initiating treatment. Do not administer ustekinumab to patients with active tuberculosis infection. Initiate treatment of latent tuberculosis prior to administering ustekinumab. Consider anti-tuberculosis therapy prior to initiation of ustekinumab in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Closely monitor patients receiving ustekinumab for signs and symptoms of active tuberculosis during and after treatment.

Dosage and Administration [1,2]:

1. **Plaque psoriasis:**

Adult subcutaneous recommended dosage

Weight Range (kilograms)	Dosage Regimen
less than or equal to 100 kg	45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks
greater than 100 kg	90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks

Pediatric patients (6 to 17 years old) subcutaneous recommended dosage: at week 0 and 4, then every 12 weeks thereafter [1]

Weight Range (kilograms)	Dosage
less than 60 kg	0.75 mg/kg
60 kg to 100 kg	45 mg
greater than 100 kg	90 mg

2. **Psoriatic arthritis (PsA):**

- Adult Subcutaneous Recommended Dosage:
  - The recommended dosage is 45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks.
  - For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dosage is 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks.

- Pediatric (6 to 17 years old) Subcutaneous Recommended Dosage:
  - Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter:

Weight Range (kilograms)	Dosage
less than 60 kg	0.75 mg/kg
60 kg to 100 kg	45 mg
greater than 100 kg	90 mg

3. **Crohn's Disease and Ulcerative colitis:**

- Initial adult intravenous recommended dosage. A single intravenous infusion using weight based dosing:

Weight Range (kilograms)	Recommended Dosage
up to 55 kg 260 mg (2 vials)	up to 55 kg 260 mg (2 vials)
greater than 55 kg to 85 kg 390 mg (3 vials)	greater than 55 kg to 85 kg 390 mg (3 vials)
greater than 85 kg 520 mg (4 vials)	greater than 85 kg 520 mg (4 vials)

- Maintenance adult subcutaneous recommended dosage: A subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

Immunizations [1]:
Prior to initiating therapy with ustekinumab, patients should receive all age-appropriate immunizations as recommended by current immunization guidelines. Patients being treated with ustekinumab should not receive live vaccines. BCG vaccines should not be given during treatment with ustekinumab or for one year prior to initiating treatment or one year following discontinuation of treatment. Caution is advised when administering live vaccines to household contacts of patients receiving ustekinumab because of the potential risk for shedding from the household contact and transmission to patient. Non-live vaccinations received during a course of ustekinumab may not elicit an immune response sufficient to prevent disease.

Discontinuing treatment [2]:

1. **Plaque psoriasis**: Consideration should be given to discontinuing treatment in patients who have shown no response up to 28 weeks of treatment.
2. **Psoriatic arthritis (PsA):** Consideration should be given to discontinuing treatment in patients who have shown no response up to 28 weeks of treatment.
3. **Crohn's Disease and Ulcerative Colitis:** Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit 16 weeks after the IV induction dose or 16 weeks after switching to the 8-weekly maintenance dose.

3.2 Requirements for Coverage

- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.
- Kindly code the ICD-10 and the CPT codes to the highest level of specificity
- Eligible clinician specialities

Eligible clinician speciality
Dermatologist
Rheumatologist
Gastroenterologist

3.3 Non-Coverage

- Not covered for visitor plan
- Age less than 6 years

3.4 Payment and Coding Rules

Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC 004	Service is not clinically indicated based on good clinical practice
MNEC 003	Diagnoses are not covered
AUTH-001	Prior approval is required and was not obtained

5. Appendices

JAWADA clinical quality KPI: not applicable

5.1 References

1. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125261s161lbl.pdf*
2. *https://www.medicines.org.uk/emc/product/7638/smpc#gref*

5.2 Revision History

Date	Change(s)
31/03/2023	Release of V1.0
05/06/2023	Update: removed colorectal surgeon