Ustekinumab

Adjudication Guideline

Rule Category: Pharmaceutical	**Ref: No:** 2023-PH-19	**Version Control:** Version No. V1.0	**Effective Date:** 1st April 2023	**Revision Date:** 7th August 2024
Approved by: Daman	**Responsible:** Medical Standards & Research	**Related Adjudication Guidelines:** NA		

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1. Abstract

1.1 For Members

Ustekinumab is a biological drug that is indicated to treat autoimmune diseases such as active psoriatic arthritis, Psoriasis, Chron's disease and Ulcerative Colitis. It should be prescribed under the supervision of a specialized healthcare profession.

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**: 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.
3. **Crohn's Disease**: 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:** 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. In Crohn's disease if therapy is interrupted, resumption of treatment with subcutaneous dosing every 8 weeks is safe and effective.

Pre-treatment Evaluation for Tuberculosis:
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 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. **Plaque psoriasis:**

- **Adults recommended dosage**

Weight Range (Kg)	Dose Strength	Dose Interval
Less than or equal to 100 kg	45 mg SC	1st loading dose: Day 1 2nd loading dose: Day 28 Maintenance: Every 12 weeks (1st maintenance dose is after 12 weeks from the 2nd dose)
Greater than or equal to 100 kg	90 mg SC	1st dose: Day 1 2nd dose: Day 28 Maintenance: every 12 weeks (1st maintenance dose is after 12 weeks from the 2nd dose)

- **Pediatric patients (6 to 17 years old) subcutaneous recommended dosage**

Weight Range (Kg)	Dose Strength	Dose Interval
Less than or equal to 60 kg	0.75 mg/kg SC	1st dose: Day 1 2nd dose: Day 28 Maintenance: every 12 weeks (counting should start 12 weeks from the 2nd dose)
Greater than 60 to 100 kg	45 mg SC	1st dose: Day 1 2nd dose: Day 28 Maintenance: every 12 weeks (counting should start 12 weeks from the 2nd dose)
Greater than or equal to 100 kg	90 mg SC	1st dose: Day 1 2nd dose: Day 28 Maintenance: every 12 weeks (counting should start 12 weeks from the 2nd dose)

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

Condition	Dose Strength	Dose Interval
PsA with mild Psoriasis **(Regardless of the weight)**	45 mg SC	1st loading dose: Day 1 2nd loading dose: Day 28 Maintenance: Every 12 weeks (1st maintenance dose is after 12 weeks from the 2nd dose)
PsA with moderate to severe Psoriasis **(Greater than 100 kg)**	90 mg SC	1st dose: Day 1 2nd dose: Day 28 Maintenance: every 12 weeks

		(1st maintenance dose is after 12 weeks from the 2nd dose)

- **Pediatric patients (6 to 17 years old) subcutaneous recommended dosage**

Weight Range (Kg)	Dose Strength	Dose Interval
Less than or equal to 60 kg	0.75 mg/kg SC	1st dose: Day 1 2nd dose: Day 28 Maintenance: every 12 weeks (counting should start 12 weeks from the 2nd dose)
Greater than 60 to 100 kg	45 mg SC	1st dose: Day 1 2nd dose: Day 28 Maintenance: every 12 weeks (counting should start 12 weeks from the 2nd dose)
Greater than or equal to 100 kg	90 mg SC	1st dose: Day 1 2nd dose: Day 28 Maintenance: every 12 weeks (counting should start 12 weeks from the 2nd dose)

3. Crohn's Disease and Ulcerative Colitis:

- **Adults recommended dose**

Weight Range (Kg)	Initial Dosage form and Strength	Maintenance Dosage form and strength	Dose Interval
up to 55 kg	260 mg IV	90 mg SC	1st dose: Day 1 2nd dose: Day 56 Maintenance: every 8 weeks (counting should start 8 weeks from the 2nd dose)
Greater than 55 to 85 kg	390 mg IV	90 mg SC	1st dose: Day 1 2nd dose: Day 56 Maintenance: every 8 weeks (counting should start 8 weeks from the 2nd dose)
Greater than 85 kg	520 mg IV	90 mg SC	1st dose: Day 1 2nd dose: Day 56 Maintenance: every 8 weeks (counting should start 8 weeks from the 2nd dose)

Immunizations:
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:
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 specialties

Eligible clinician speciality
Dermatology
Rheumatology
Gastroenterology

3.3 Non-Coverage

- Visitor Plan
- Basic Plan as per the formulary
- Age below 6 years old

3.4 Payment and Coding Rules

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

4. Denial Codes

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	Service is not clinically indicated based on good clinical practice~MNEC-003
AUTH-001	Prior approval is required and was not obtained
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender~CODE-014

5. Appendices

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	Creation of Adjudication Guideline-External Instruction Template.
05/06/2023	Update: removed colorectal surgeon
07/08/2024	Review and Edit Dosage form and strength tables

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