

# STANDARD MEDICARE PART B 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.

##### FDA-Approved Indications<sup>1</sup>

- A. For the treatment of patients 6 years or older with moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy.
- B. For the treatment of adult patients with active psoriatic arthritis (PsA), alone or in combination with methotrexate.
- C. For the treatment of adult patients with moderately to severely active Crohn's disease (CD).
- D. For the treatment of adult patients with moderately to severely active ulcerative colitis.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

##### **A. Plaque Psoriasis<sup>1</sup>**

Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis (Ps).

##### **B. Psoriatic Arthritis<sup>1</sup>**

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

##### **C. Crohn's Disease<sup>1</sup>**

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease (CD).

##### **D. Ulcerative colitis<sup>1</sup>**

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

#### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with Stelara

<b>Reference number</b>
2393-A

2. Stelara is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy.

#### **IV. REFERENCE**

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; December 2020.