J0129

ABATACEPT/ORENCIA

FACT SHEET

Description

HCPCS J0129 (Injection, abatacept, 10 mg)

Abatacept (Orencia®) is a selective T cell costimulation moderator approved by the Food and Drug Administration (FDA) for the treatment of patients with:

- Adult Rheumatoid Arthritis (RA)
- Adult Psoriatic Arthritis (PsA)
- Juvenile Idiopathic Arthritis (pJIA)

Accepted Dosage and Administration

Intravenous Administration for Adult RA (2.1) and Adult PsA (2.3)

Administer at 0, 2, and 4 weeks, and every 4 weeks thereafter:

Body Weight of Patient	Dose	Number of Vials
Less than 60 kg	500 mg	2
60 to 100 kg	750 mg	3
More than 100 kg	1000 mg	4

Subcutaneous Use for Adult RA (2.1)

- Prior to the first subcutaneous dose, may administer an optional loading dose as a single intravenous infusion as per body weight categories above.
- Administer 125 mg by subcutaneous injection once weekly (within a day of the intravenous infusion if infusion given).
- Patients switching from intravenous use to subcutaneous use, administer first subcutaneous dose instead of next scheduled intravenous dose.

Subcutaneous Use for Adult PsA (2.3)

- Administer 125 mg by subcutaneous injection once weekly without an intravenous loading dose.
- Patients switching from intravenous use to subcutaneous use, administer first subcutaneous dose instead of next scheduled intravenous dose.

Intravenous Use for pJIA in Pediatric Patients ≥6 Years Old (2.2)

- Pediatric patients weighing <75 kg administer 10 mg/kg intravenously and those weighing ≥75 kg administer the adult intravenous dosing regimen (not to exceed a maximum dose of 1000 mg)
- Subsequently administer infusions at 2 and 4 weeks and every 4 weeks thereafter

Subcutaneous Use for pJIA in Pediatric Patients ≥2 Years Old (2.2)

Administer subcutaneously without an intravenous loading dose:

Body Weight of Patient	Dose (once weekly)
10 kg to less than 25 kg	50 mg
25 kg to less than 50 kg	87.5 mg
50 kg or more	125 mg

Medical Necessity

Medicare Part B does generally not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the coverage of some self-administered drugs.

A/B MACs (A), (B), and (HHH), are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual A/B MAC (A), (B), or (HHH) must make its own individual determination on each drug. A/B MACs (A), (B), and (HHH) must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary.

For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered. For example, an injectable drug used to treat migraine headaches is usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

Documentation must support compliance with Medicare rules and regulations such as: diagnoses; appropriate orders and signatures; administration/frequency/deliverance of the service; as well as correct coding and billing of the drug, per medical necessity.

Documentation must support provider specialty of 66 Rheumatology or 07 Dermatology.

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Progress note or medical record should support one of the above listed conditions with 3-month trial of oral agent, IV agent that failed, or other indication.

Supporting Documentation

Documentation of frequency, as noted above, must support accepted prescribing guidelines.

Documentation must indicate if after initial intravenous (IV) dose, subcutaneous (SQ) is appropriate for future doses or contain a stated medically necessary reason **not** to give SQ such as:

- Age related (17 years and younger IV only)
- Patient/Patient Care Giver mentally or medically impaired to self-inject (crippled hands), to learn self-injections (dementia), no available caregivers
- Patient may have condition flare and requires IV dose(s) to obtain remission
- Patient may have skin condition more susceptible for infection

A signed order must be present for the drug by the approved specialty provider or intent to order within the progress note.

In addition, a purchase order with the name of the drug and information of the vial should be included.

If applicable, an Advance Beneficiary Notice (ABN) should be included in the record.

Appropriate Signatures

- Signature and credentials of person performing the service must meet CMS requirements
- Amendments/corrections/delayed entries are properly identified

For more information regarding signature requirements, please view the following resources:

- CGS Administrators, LLC, J15 Part B Medical Review https://www.cgsmedicare.com/partb/mr/signatures.html
- https://www.cgsmedicare.com/partb/cert/signatures.pdf
- CMS MLN Fact Sheet, Complying with Medicare Signature Requirements. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/signature_requirements_fact_sheet_icn905364.pdf
- CMS IOM Pub. 100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.3.2.4, Signature Requirements. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf

Documentation of Administration

The following administration details must be documented within the record:

- Patient weight
- Name of the drug
- Date of Service
- Patient consent
- Documentation to support drug was administered to the correct beneficiary
- Amount of the drug administered per the order
- Documentation to support route drug was administered (IV or SQ)
- Documentation containing location the IV was administered
- Amount of the drug wasted, signature of person wasting, and appropriate modifier (JW) if applicable

References

- IOM 100-02, Chapter 15 – Covered Medical and Other Health Services, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
- IOM 100-04, Chapter 17 – Drugs and Biologicals, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf
- IOM 100-08, Chapter 3 – Verifying Potential Errors and Taking Corrective Actions, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf
- Notification of Service Specific Post Payment Review for Drugs, https://www.cgsmedicare.com/partb/pubs/news/2020/08/cope18504b.html
- Orencia Prescribing Information, https://packageinserts.bms.com/pi/pi_orencia.pdf