FACT SHEET

J0129
ABATACEPT/ORENCIA

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
- Prophylaxis for Acute Graft versus Host Disease

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

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.

The concomitant use of ORENCIA with other potent immunosuppressants [e.g., biologic disease modifying antirheumatic drugs (bDMARDs), Janus kinase (JAK) inhibitors] is not recommended.

Documentation must support provider specialty of 66 Rheumatology, 07 Dermatology, 82 Hematology or 83 Hematology/Oncology.

Adult Rheumatoid Arthritis

Documentation must support treatment of patient with moderately to severely active rheumatoid arthritis.

Polyarticular Juvenile Idiopathic Arthritis

Documentation must support patient with moderately to severely active polyarticular juvenile idiopathic arthritis.

Psoriatic Arthritis

Documentation must support PsA is in active disease process via an objective scale to include but not limited to Disease Activity Index for Psoriatic Arthritis (DAPSA) or Psoriatic Arthritis Disease Activity Score.

Subcutaneous Injection

Documentation must support proper training in subcutaneous injection techniques provided to patient or caregiver on administration of subcutaneous injection of ORENCIA.

This Fact Sheet is for informational purposes only and is not intended to guarantee payment for services, all services submitted to Medicare must meet Medical Necessity guidelines. The definition of "medically necessary" for Medicare purposes can be found in Section 1862(a)(1)(A) of the Social Security Act – Medical Necessity (http://www.ssa.gov/OP_Home/ssact/title18/1862.htm).

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Supporting Documentation

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

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)
- Orencia Prescribing Information (https://packageinserts.bms.com/pi/pi_orencia.pdf)

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