DRUG POLICY

Pasatru® (garetosmab-grts)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Pasatru is indicated to reduce formation of new heterotopic ossification lesions and clinician-assessed flare-ups in adults with fibrodysplasia ossificans progressiva (FOP).

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For initial requests:
    a. Genetic test results confirming diagnosis of fibrodysplasia ossificans progressiva (FOP) with documented activin receptor type 1 (ACVR1) variant (e.g., R206H).
    b. Chart notes or medical record documentation supporting signs and symptoms of FOP (i.e., congenital malformation of the great toe AND episodic soft-tissue swelling and/or ectopic ossification in ligament or muscle tissue).
    c. Chart notes or medical record documentation supporting signs and symptoms of active disease within the past 12 months (e.g., FOP flare-ups, worsening of joint function, radiographic progression of heterotopic ossification lesions).

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2. For continuation requests:
    a. Chart notes or medical record documentation supporting benefit from therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who is experienced in the treatment of fibrodysplasia ossificans progressiva (FOP) (e.g., endocrinologist, orthopedist, rheumatologist, neurologist)

Criteria for Initial Approval

Fibrodysplasia Ossificans Progressiva

1. Authorization of 12 months may be granted to reduce formation of new heterotopic ossification lesions and clinician-assessed flare-ups of FOP in adult members when all of the following criteria are met:

    a. Member has a confirmed diagnosis of FOP by genetic test indicating the member has a pathogenic activin receptor type 1 (ACVR1) FOP-causing variant (e.g., R206H).
    b. Member has signs and symptoms of FOP (i.e., congenital malformation of the great toe AND episodic soft-tissue swelling and/or ectopic ossification in ligament or muscle tissue).
    c. Member has evidence of active disease within the past 12 months (e.g., FOP flare-ups, worsening of joint function, radiographic progression of HO lesions).
    d. Member has a Cumulative Analog Joint Involvement Scale (CAJIS) score less than or equal to 19 at baseline.
    e. Member has no active or recent malignancy.
    f. Member has no significant uncontrolled comorbid illness (e.g., cardiac, neurologic, rheumatologic).
    g. Females of reproductive potential should have a negative pregnancy test.
    h. Member is not currently breastfeeding, pregnant, or planning pregnancy.
    i. The requested medication will not be used in combination with palovarotene (Sohonos)

Continuation of Therapy

Fibrodysplasia Ossificans Progressiva

1. **Authorization of 12 months may be granted for continued treatment in adult members requesting reauthorization when all of the following criteria are met:**

    a. The member is experiencing benefit from therapy as evidenced by disease improvement or disease stability, such as stability or reduction in the volume of new heterotopic ossification or reduced frequency or severity of clinician-assessed flare-ups.
    b. Member has had no serious adverse event that would contraindicate continued therapy (e.g. serious uncontrolled epistaxis, serious skin/soft-tissue infection)
    c. The member is not currently breastfeeding, pregnant, or planning pregnancy.
    d. The requested medication will not be used in combination with palovarotene (Sohonos).

Other

Pasatru (geretosmab-grts) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

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Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Pasatru (garetosmab-grts) 300 mg/5 mL single-dose vial	4 vials per 28 days	10 mg/kg by intravenous infusion once every 4 weeks. The dosage may be decreased to 3 mg/kg once every 4 weeks if 10 mg/kg is not tolerated.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3590 - Unclassified biologics
- C9399 - Unclassified drugs or biologics (for hospital outpatient department claims only)

REFERENCES

- Pasatru [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2026.
- Genetic and Rare Diseases Information Center (GARD). Fibrodysplasia Ossificans Progressiva. Rare Disease Database. Last updated June 2026. Accessed August 26, 2026.
- A Study to Assess Safety, Tolerability and Efficacy of Garetosmab Versus Placebo Administered Intravenously in Adult Participants With Fibrodysplasia Ossificans Progressiva (OPTIMA). ClinicalTrials.gov identifier NCT05394116. Updated July 17, 2026. Accessed August 31, 2026.
- Kaplan FS, Al Mukaddam M, Baujat G, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP. 2019;1:1-111.

POLICY HISTORY

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