

Specialty Guideline Management

Pasatru

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Pasatru	garetosmab-grts

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 Indication¹

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

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

Initial requests

- Genetic test results confirming diagnosis of fibrodysplasia ossificans progressiva (FOP) with documented activin receptor type 1 (ACVR1) variant (e.g., R206H).

Reference number(s)
7590-A

- 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).
- 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).

Continuation requests

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).

Coverage Criteria

Fibrodysplasia Ossificans Progressiva (FOP)¹⁻⁴

Authorization of 12 months may be granted for reduction in the volume of new heterotopic ossification (HO) lesions and clinician-assessed flare-ups of FOP in adult members (18 years of age and older) when all of the following criteria are met:

- 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).
- 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).
- 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).
- Member has a Cumulative Analog Joint Involvement Scale (CAJIS) score less than or equal to 19 at baseline.
- Member has no active or recent malignancy.
- Member has no significant uncontrolled comorbid illness (e.g., cardiac, neurologic, rheumatologic).
- Females of reproductive potential should have a negative pregnancy test.
- Member is not currently breastfeeding, pregnant, or planning pregnancy.
- The requested medication will not be used in combination with palovarotene (Sohonos).

Continuation of Therapy¹⁻⁴

Authorization of 12 months may be granted for continued treatment in adult members (18 years of age and older) requesting reauthorization for an indication listed in the coverage criteria when all of the following criteria are met:

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

References

1. Pasatru [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2026.
2. Genetic and Rare Diseases Information Center (GARD). Fibrodysplasia Ossificans Progressiva. Rare Disease Database. Last updated June 2026. Accessed August 26, 2026.
<https://rarediseases.info.nih.gov>
3. A Study to Assess Safety, Tolerability and Efficacy of Garetosmab Versus Placebo Administered Intravenously (IV) in Adult Participants With Fibrodysplasia Ossificans Progressiva (FOP) (OPTIMA). ClinicalTrials.gov identifier: NCT05394116. Updated July 17, 2026. Accessed August 31, 2026.
<https://clinicaltrials.gov/study/NCT05394116>
4. 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.