Pasatru™ (garetosmab-grts)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1200 mg (4 vials) every 4 weeks

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria [1-3]

- Member does NOT have any FDA labeled contraindications to the requested agent (e.g., pregnancy); **AND**
- Females of reproductive potential must have a negative pregnancy test prior to initiating treatment and will use effective contraception during treatment and for six months after the last dose; **AND**
- Member will avoid agents and/or circumstances that will predispose to soft-tissue injury, to the extent possible (e.g., intramuscular injections, arterial punctures, dental procedures, procedures related to anesthesia, biopsies, removal of heterotopic bone, nonemergent surgical procedures, contact sports, overstretching of soft tissues, muscle fatigue, falls, etc.); **AND**
- Will be used as single agent therapy; **AND**

Fibrodysplasia Ossificans Progressiva (FOP) † Φ [1-3]

- Member has an established diagnosis of fibrodysplasia ossificans progressiva (FOP) as confirmed by the following findings:
  - Clinical (e.g., congenital hallux valgus deformity that is most often bilateral, progressive heterotopic ossification, limb reduction defects that may affect the fingers in atypical or nonclassical FOP); **AND**

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- Imaging [e.g., radiographs of the halluces demonstrate short, malformed first metatarsals and a single dysplastic phalanx; radiographs of affected areas demonstrate heterotopic ossification (extraosseous bone formation)]; **AND**
- Identification of a heterozygous pathogenic (or likely pathogenic) variant in the *ACVR1* gene by molecular genetic testing; **AND**

- Used to reduce formation of new heterotopic ossification lesions and clinician-assessed flare-ups

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2]

Prior authorization validity may be renewed based on the following criteria:

- Member continues to meet universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe skin and soft tissue infections, severe epistaxis etc.; **AND**
- Member has shown a beneficial response to treatment as evidenced by ANY of the following:
  - Reduction, stabilization, or slowing of the rate of formation of new heterotopic ossification (HO) lesions
  - Reduction or improvement in the signs and symptoms of, or number of flare-ups as compared to baseline

V. Dosage/Administration [1]

Indication	Dose
Fibrodysplasia Ossificans Progressiva (FOP)	The recommended starting dose is 10 mg/kg administered as an intravenous infusion over 60 minutes once every 4 weeks.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals

NDC:

- Pasatru 300 mg/5 mL (60 mg/mL) solution in a single-dose vial: 61755-0012-xx

VII. References

1. Pasatru [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; August 2026. Accessed September 2026.

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2. OPTIMA -ClinicalTrials.gov. **NCT05394116**. A Phase 3 Randomized, Placebo-Controlled Study to Assess Safety, Tolerability, and Efficacy of Garetosmab in Patients With Fibrodysplasia Ossificans Progressiva. | ClinicalTrials.gov.
3. Akesson LS, Savarirayan R. Fibrodysplasia Ossificans Progressiva. 2020 Jun 11 [Updated 2024 May 23]. In: Adam MP, Bick S, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026. Available from: https://www.ncbi.nlm.nih.gov/books/NBK558090/
4. Kaplan FS, Al Mukaddam M, Baujat G, et al; International Clinical Council on FOP. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. *Proc Intl Clinc Council FOP*. 2024;3:1-159
5. Kaplan FS, Al Mukaddam M, Baujat G, et al. Medical guidelines for fibrodysplasia ossificans progressiva. JBMR Plus. 2025;9(11):ziaf150. doi: 10.1093/jbmrpl/ziaf150

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M61.10	Myositis ossificans progressiva, unspecified site
M61.111	Myositis ossificans progressiva, right shoulder
M61.112	Myositis ossificans progressiva, left shoulder
M61.119	Myositis ossificans progressiva, unspecified shoulder
M61.121	Myositis ossificans progressiva, right upper arm
M61.122	Myositis ossificans progressiva, left upper arm
M61.129	Myositis ossificans progressiva, unspecified upper arm
M61.131	Myositis ossificans progressiva, right forearm
M61.132	Myositis ossificans progressiva, left forearm
M61.139	Myositis ossificans progressiva, unspecified forearm
M61.141	Myositis ossificans progressiva, right hand

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ICD-10	ICD-10 Description
M61.142	Myositis ossificans progressiva, left hand
M61.143	Myositis ossificans progressiva, unspecified hand
M61.144	Myositis ossificans progressiva, right finger(s)
M61.145	Myositis ossificans progressiva, left finger(s)
M61.146	Myositis ossificans progressiva, unspecified finger(s)
M61.151	Myositis ossificans progressiva, right thigh
M61.152	Myositis ossificans progressiva, left thigh
M61.159	Myositis ossificans progressiva, unspecified thigh
M61.161	Myositis ossificans progressiva, right lower leg
M61.162	Myositis ossificans progressiva, left lower leg
M61.169	Myositis ossificans progressiva, unspecified lower leg
M61.171	Myositis ossificans progressiva, right ankle
M61.172	Myositis ossificans progressiva, left ankle
M61.173	Myositis ossificans progressiva, unspecified ankle
M61.174	Myositis ossificans progressiva, right foot
M61.175	Myositis ossificans progressiva, left foot
M61.176	Myositis ossificans progressiva, unspecified foot
M61.177	Myositis ossificans progressiva, right toe(s)
M61.178	Myositis ossificans progressiva, left toe(s)
M61.179	Myositis ossificans progressiva, unspecified toe(s)
M61.18	Myositis ossificans progressiva, other site
M61.19	Myositis ossificans progressiva, multiple sites

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	Wellpoint Federal
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	Wellpoint Federal
15	KY, OH	CGS Administrators, LLC

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