Velaglucerase alfa (VPRIV®)	Place of Service Office Administration Home Infusion Administration Infusion Center Administration Outpatient Facility Administration HCPCS: J3385 per 100 units

Condition listed in policy *(see criteria for details)*

- Gaucher disease, Type 1

AHFS therapeutic class: Enzymes

Mechanism of action: Velaglucerase alfa, a hydrolytic lysosomal glucocerebroside-specific enzyme, catalyzes the hydrolysis of glucocerebroside, reducing the amount of accumulated glucocerebroside

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for VPRIV® (velaglucerase alfa) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Gaucher's disease, Type I

1. Diagnosis of Gaucher's disease Type I, **AND**
2. Patient has at least one of the following:
    a. Anemia, OR
    b. Thrombocytopenia, OR
    c. Bone disease (e.g., lesions, fractures, osteopenia, osteonecrosis, osteosclerosis), OR
    d. Hepatosplenomegaly or splenomegaly, OR
    e. Symptomatic disease (including abdominal or bone pain, fatigue, physical function limitation, growth retardation in children, or malnutrition/cachexia)

    AND
3. Not being used in combination with other therapies for Type 1 Gaucher disease [ERT taliglucerase (Elelyso), imiglucerase (Cerezyme), SRT eliglustat (Cerdelga), miglustat (Zavesca)]

Covered Doses
Up to 120 U/kg/month

Coverage Period
Indefinite

ICD-10:
E75.22

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for VPRIV® (velaglucerase alfa) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:
400 unit (single-use vials to be reconstituted)

Anemia Thresholds. Table 1.

Age and Sex	Reference range (Mean g/dl)	> 2 SD below mean = anemia g/dl for Peds	"High Risk" >2 gm below lower limit of normal for age and sex for children	*Pastores 2004* Definition of Anemia w/ Gaucher Treatment Goals are to increase above these levels in 12-24 mos
0.5-2 years	12.0	<11.0	< 9.0	<9.5
2-6 years	12.5	<11.5	< 9.5	<10.5
6-12 years	13.5	<11.5	< 9.5	<10.5
Female 12-18 years	14.0	<12.0	< 10.0	<11.0
Male 12-18 years	14.5	<13.0	< 11.0	<12.0
Female > 18 years (range)	13.8 (12.3–15.3)		Refer to Guideline For High risk criteria in adults	<11.0
Male > 18 years (range)	15.7 (14.0-17.5)			<12.0

Reference: Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic Goals in the Treatment of Gaucher Disease. Semin Hematol 41 (suppl 5):4-14. 2004.

(6) References

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- Charrow J, Andersson HC, Kaplan P, et al. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations. J Pediatr 2004;144: 112–120.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Mistry PK, Cappellini MD, Lukina E, et al. A reappraisal of Gaucher disease – Diagnosis and disease management algorithms (Consensus conference) 2010. Am J Hematol 2011; 86(1):110-5.
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(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 3Q2024
Changes from previous policy version:

- Section (2): Gaucher's disease Type 1 – Removed step therapy with Cerezyme
  Rationale: Cost effective therapeutic alternative