VPRIV® Reimbursement:

a coding guide for healthcare providers

VPRIV® velaglucerase alfa for injection

Completing forms with the appropriate codes is a necessary part of the reimbursement process and is the responsibility of the healthcare providers who are administering VPRIV. This coding guide details some of the codes that may be required for billing. Please be aware that codes and billing procedures sometimes change. Before completing a reimbursement form, be sure to obtain the most up-to-date information

KEY CODES AND SERVICES FOR BILLING

ICD-10-CM (International Classification of Diseases, 10th Revision, Clinical Modification)

- **E75.22** – Gaucher disease[1]

NDC (National Drug Code)

- **54092-701-04**[2]
- 11 digit billing format: **54092070104**[2]

CPT-4 (CPT – Current Procedural Terminology)*

** CPT is a registered trademark of the American Medical Association.*

- **96365** – IV infusion for therapy/prophylaxis, administered by a physician or under the direct supervision of a physician, up to 1 hour[3]
- **96366** – Each additional hour, up to 8 hours[3]

HCPCS (Healthcare Common Procedure Coding System)

- **J3385** – Injection, Velaglucerase alfa, 100 units[4]
- **Q0081** – Non-chemotherapeutic infusion therapy (hospital only)[5]
- **S9357** – Home infusion therapy, enzyme replacement intravenous therapy (e.g., imiglucerase); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately) per diem.[6]

REVENUE CODES

Hospitals must use the following revenue code on Form UB-04:

- **0636** – Drugs and biologicals requiring an HCPCS code[7]

Other revenue codes that may be used by hospitals include:

- 0258 – IV solutions[8]
- 0260 – General IV therapy service[8]
- 0261 – Infusion pump[8]

INDICATION

VPRIV® (velaglucerase alfa) for injection is indicated for long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease.

IMPORTANT SAFETY INFORMATION

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.
Initiate VPRIV in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment.
If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue VPRIV and immediately initiate appropriate medical treatment., including use of epinephrine. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.

Please see Additional Important Safety Information on page 2 of this guide, and click here for Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Life-threatening hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with enzyme replacement therapies, including VPRIV. VPRIV-treated patients have had these reactions occur in clinical studies and postmarketing experience.

Hypersensitivity reactions were the most commonly observed adverse reactions in patients treated with VPRIV in clinical studies. Patients were not routinely pre-medicated prior to infusion of VPRIV. The most commonly observed symptoms of hypersensitivity reactions were: headache, dizziness, hypotension, hypertension, nausea, fatigue/asthenia, and pyrexia. Hypersensitivity reactions in the clinical trials include any event considered related to and occurring within up to 24 hours of VPRIV infusion, including one case of anaphylaxis. Generally the reactions were mild and, in treatment-naïve patients, onset occurred mostly during the first 6 months of treatment and tended to occur less frequently with time. Additional hypersensitivity reactions of chest discomfort, dyspnea, pruritus and vomiting have been reported in post-marketing experience. In some cases vomiting can be serious, requiring hospitalization and/or drug discontinuation.

Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy. Administration of VPRIV should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis. Initiate VPRIV in a healthcare setting with appropriate medical monitoring and support measures including access to cardiopulmonary resuscitation equipment.

Management of hypersensitivity reactions should be based on severity of the reaction, such as slowing the infusion rate, treatment with medications such as antihistamines, antipyretics and/or corticosteroids, and/or stopping and resuming treatment with increased infusion time. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue VPRIV and immediately initiate appropriate medical treatment, including use of epinephrine. In cases where patients have exhibited symptoms of hypersensitivity to velaglucerase alfa or excipients in the drug product or to other enzyme replacement therapy, pre-treatment with antihistamines and/or corticosteroids may prevent subsequent reactions. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.

The most common adverse reactions during clinical studies (in ≥10% of patients) were hypersensitivity reactions, headache, dizziness, abdominal pain, nausea, back pain, joint pain, prolonged activated partial thromboplastin time (aPTT), fatigue/asthenia, and pyrexia. In clinical studies, the overall frequency of adverse events was generally higher in the population naïve to enzyme replacement therapy (ERT) than in the population switched from imiglucerase to VPRIV.

The safety and efficacy profiles were similar in pediatric (ages 4 to 17) and adult patients. The safety of VPRIV has not been established in patients under 4 years of age. Adverse reactions more commonly seen in pediatric patients compared to adult patients include (>10% difference): rash, prolonged aPTT, and pyrexia. The adverse reaction profile in elderly patients was consistent with that previously observed across pediatric and adult patients. In general, dose selection for an elderly patient should be approached cautiously, considering comorbid conditions.

As with all therapeutic proteins, there is a potential for immunogenicity. In clinical studies, 1 of 54 (2%) enzyme treatment-naïve patients treated with VPRIV developed IgG class antibodies (neutralizing in an *in vitro* assay). One additional patient developed IgG antibodies to VPRIV during an extension study. It is unknown if the presence of IgG antibodies to VPRIV is associated with a higher risk of infusion reactions. Patients with an immune response to other ERTs who are switching to VPRIV should continue to be monitored for antibodies to VPRIV.

To report SUSPECTED ADVERSE REACTIONS, contact Medical Information at 1-866-888-0660, option 2 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here for Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

REFERENCES

1. cdc.gov [Online] https://icd10cmtool.cdc.gov/?fy=FY2019&q=gaucher%20disease. Accessed 03 July 2024. **2.** ndclist.com [Online] https://ndclist.com/ndc/54092-701/package/54092-701-04. Accessed 03 July 2024. **3.** Centers for Medicare & Medicaid Services. cms.gov. [Online] https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2012-Aug-Final-Supervision-Decisions.pdf. Accessed 03 July 2024. **4**. hipaaspace.com [Online] http://www.hipaaspace.com/medical_billing/coding/healthcare.common.procedure.coding.system/J3385. Accessed 03 July 2024. **5.** hipaaspace.com. [Online] https://www.hipaaspace.com/Medical_Billing/Coding/Healthcare.Common.Procedure.Coding System/Q0081. Accessed 03 July 2024. **6.** hipaaspace.com [Online] https://www.hipaaspace.com/Medical_Billing/Coding/Healthcare.Common.Procedure.Coding.System/S9357. Accessed 03 July 2024. **7.** findacode.com [Online] https://www.findacode.com/ub04-revenue/ub04-revenue-cms-1450-codes-06-group.html. Accessed 03 July 2024. **8.** findacode.com [Online] https://www.findacode.com/ub04-revenue/ub04-revenue-cms-1450-codes-02-group.html. Accessed 03 July 2024.