# Prior Authorization Checklist

# Infilbray™

venglustat 6 mg | 15 mg tablets

## The First and Only Therapy to Deliver a Neurologic Breakthrough in GD3 in Patients Weighing at Least 15 kg

This guide is provided for informational purposes only and does not constitute legal or reimbursement advice. For insurance plan-specific criteria, **CareConnect™ Personalized Support Services** can help you **navigate insurance processes** regarding treatment access on behalf of your patients.

## Indication

INFILBRAY™ (venglustat) is indicated for the treatment of neurological manifestations of Type 3 Gaucher disease (GD3) in patients weighing at least 15 kg.

## Important Safety Information

### Warnings and Precautions:

#### Suicidal Ideation and Behavior:

Suicidal ideation and behavior have been reported in patients with GD3 receiving INFILBRAY and in unapproved populations receiving another formulation of venglustat, both with and without a history of psychiatric disorders. Assess patients' underlying risk of psychiatric disorders prior to initiation and monitor for depressive symptoms or suicidal thoughts during treatment. Use caution when prescribing to patients with a history of psychiatric disorders.

**Please see Important Safety Information throughout and Full Prescribing Information for INFILBRAY.**

# Prior Authorization Checklist for Infilbray

Although requirements vary by insurance plan, below are common criteria that may be requested for Infilbray. **If you have questions about the prior authorization (PA) process, please feel free to call CareConnect at 1-800-745-4447, option 3.**

## 1. Benefits investigation

- ○ PA requirements vary between plans. Contact the insurance plan to understand the process, utilization management criteria, duration of approval, and other relevant information

## 2. Common PA requirements

### Patient/HCP information

- ○ Name
- ○ Date of birth
- ○ Insurance plan
- ○ HCP name
- ○ HCP identification number

### Diagnosis information

- ○ Diagnosis/ICD-10-CM code[a]
  - E75.22, Description: Gaucher disease
- ○ Deficiency of acid ß-glucosidase activity
- ○ Patient weight of at least 15 kg
- ○ **Presence and severity of specific neurological symptoms** associated with Gaucher disease type 3 (GD3) (eg, ataxia, visuospatial/constructional abilities, language, attention); include quantitative assessments if possible

**Insurance plans may require documentation of specific information and/or HCP attestation.**

### Treatment information

- ○ Documentation of prior therapies, if applicable
- ○ Any relevant clinical/chart notes
- ○ For reauthorization, documentation of improvement or no worsening in neurological symptom(s) of GD3

**Be sure to provide relevant clinical support, such as clinical notes, laboratory results, etc.**

[a]The *ICD-10-CM* code is not all-inclusive. Appropriate codes vary by patient, insurance plan, and setting for care. Correct coding is the responsibility of the HCP submitting the claim. Sanofi does not guarantee coverage or reimbursement.

*ICD-10-CM, International Classification of Diseases, Tenth Edition, Clinical Modification.*

## Important Safety Information (cont'd)

**Warnings and Precautions:** (cont'd)

**Suicidal Ideation and Behavior:** (cont'd)

Inform patients or caregivers of the potential for behavioral and mood changes and to seek medical attention for manifestations of suicidal ideation and behavior, new onset or worsening depression, or other mood changes. Consider changing the therapeutic regimen, including possibly discontinuing INFILBRAY, if such events occur.

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# Prior Authorization Checklist for Infilbray (cont'd)

## 3. Additional documentation

- ○ If history of seizures (other than myoclonic seizures), seizures are well controlled with medication that is not a strong or moderate inducer or inhibitor of CYP3A

**Including this documentation can help facilitate a PA submission for all insurance plans.**

## 4. PA submission

- ○ Include a statement of medical necessity and letter of intent to help avoid delays
- ○ Use the most up-to-date PA form with the insurance plan
- ○ Verify that the PA (total number of pages) was received
- ○ Find out the typical length of time the PA review process takes with the patient's insurance plan

**An expedited PA review can be requested based on patient need, which may require additional documentation.**

**Help your patients get started on their Infilbray access journey with the Patient Enrollment Form**

## Important Safety Information (cont'd)

**Warnings and Precautions:** (cont'd)

**Lens Opacification in Pediatric Patients:**
Lens opacification may occur in pediatric patients treated with INFILBRAY. In pediatric patients, perform ophthalmological assessment prior to initiation and annually during treatment. Advise pediatric patients and caregivers to report any visual disturbances during treatment.

**Embryofetal Toxicity:**
Based on animal studies, INFILBRAY may cause fetal harm when administered to a pregnant woman. Prior to initiation, verify pregnancy status in females of reproductive potential and advise them of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment and for 11 days after the last dose.

**Adverse Reactions:**
The most common adverse reactions reported in ≥10% of INFILBRAY-treated GD3 patients aged ≥12 years were diarrhea, splenomegaly, nausea, depression, gastroenteritis, and vomiting.

**Please see Important Safety Information throughout and Full Prescribing Information for INFILBRAY.**

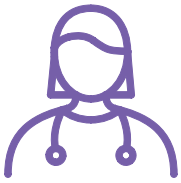
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# Handling potential PA request denials

## Common reasons for coverage denials include



**Lack of demonstrated medical necessity**



**Out-of-network provider**



**Incorrect or missing information**



**Administrative errors**

## Steps to take if a PA request is denied

### To prepare for an appeal

- ○ Revisit the insurance plan's submission requirements and confirm that the initial claim was submitted correctly
- ○ Review the insurance plan's appeal process and deadlines (deadline is usually 6 months)
- ○ Contact the insurance plan to request the appeal form and verify any documentation requirements
- ○ Complete any required insurance plan-specific appeal forms, along with the Infilbray letter of appeal and supporting documentation, to support the medical necessity and rationale for treating the patient with Infilbray

The recommendations offered in this document do not guarantee approval of PA requests or reimbursement, nor should they be construed as medical advice. Always consult with patients' insurance plans regarding specific requirements for PA submission.

## Important Safety Information (cont'd)

### Drug Interactions:

**Strong CYP3A Inhibitors:** Avoid concomitant use with INFILBRAY. Strong CYP3A inhibitors increase venglustat exposure, which may increase the risk of adverse reactions. If concomitant use is unavoidable, reduce INFILBRAY dosage.

**Strong or Moderate CYP3A Inducers:** Avoid concomitant use with INFILBRAY. Strong or moderate CYP3A inducers decrease venglustat exposure, which may result in decreased efficacy. If concomitant use is unavoidable, monitor for reduced effectiveness.

**Please see Important Safety Information throughout and Full Prescribing Information for INFILBRAY.**

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