

Gozellix[®] is fully reimbursed

Gozellix has Transitional Pass-Through (TPT) status under its permanent HCPCS code (A9616). TPT status is effective from October 1, 2025, through September 2028.

WHAT THIS MEANS FOR YOUR SITE

Separate Payment

Gozellix is reimbursed at WAC +6% (~\$7,027.80 for a standard 6-mCi dose, or ASP +6% if ASP is established) beginning Q4 2025.

Continuation of Care

Gozellix is the only Ga-68 PSMA imaging agent currently on TPT status.

Gozellix is a strongly positioned and reimbursed imaging agent for suspected metastatic or recurrent prostate cancer.

To learn more about Gozellix, reach out to a Telix representative.

INDICATIONS AND USAGE

GOZELLIX, after radiolabeling with Ga-68, is for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- With suspected metastasis who are candidates for initial definitive therapy
- With suspected recurrence based on elevated serum prostate-specific antigen (PSA) level

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Risk for Misinterpretation

Image interpretation errors can occur with GOZELLIX PET. A negative image does not rule out the presence of prostate cancer, and a positive image does not confirm the presence of prostate cancer. Gallium Ga-68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes such as Paget's disease, fibrous dysplasia, and osteophytosis. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Imaging Prior to Initial Definitive or Suspected Recurrence Therapy

The performance of GOZELLIX for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of GOZELLIX for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score.

Radiation Risks

Gallium Ga-68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and healthcare providers. Advise patients to hydrate before and after administration and to void frequently after administration.

Hypersensitivity Reactions to Sulfites

Ascorbic Acid Stabilizer contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes

in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

ADVERSE REACTIONS

The safety of gallium Ga-68 gozetotide was evaluated in 960 patients in the PSMA-PreRP and PSMA-BCR studies, each receiving one dose of gallium Ga-68 gozetotide. The average injected activity was 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi). The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of <1%.

DRUG INTERACTIONS

Androgen deprivation therapy and other therapies targeting the androgen pathway

Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium Ga-68 gozetotide in prostate cancer. The effect of these therapies on performance of gallium Ga-68 gozetotide PET has not been established.

Please note that this information is not comprehensive. Please see the Full Prescribing Information at gozellix.com/prescribinginformation

You are encouraged to report suspected adverse reactions of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report adverse reactions to Telix Pharmaceuticals (US) by calling 1-844-455-8638 or emailing pharmacovigilance@telixpharma.com.

Please contact the Telix Customer Service team to get access to Telix products, request information/status on orders or expedite an order, schedule product onboarding for your site or request technical support, or any other general inquiry. Our customer support team is available to provide any resources you may need.

Customer Service Telephone (Mon-Fri, 8:00 AM – 5:00 PM ET): 463-235-2159

Customer Service Email (response time less than 1 business day): customerservice.americas@telixpharma.com

The Telix Pharmaceuticals and Gozellix[®] names and logos are trademarks of Telix Pharmaceuticals Limited and its affiliates.

© 2025 Telix Pharmaceuticals Ltd. All rights reserved.
US-GOZ-2500094 12/2025