

Coherus BioSciences is pleased to announce CMS has granted LOQTORZI[®] (toripalimab-tpzi) a product-specific J Code

J3263

EFFECTIVE JULY 1, 2024*

HCPCS Code	Description	Billable Units	NDC
J3263	Injection, toripalimab-tpzi, 1 mg	1 mg	70114-0340-01

For additional information:



Visit LOQTORZISolutions.com



Call 1-844-483-3692



Contact your LOQTORZI
Sales Representative or
Field Reimbursement Manager

*J3263 should be used for LOQTORZI administered on or after July 1, 2024. For dates of service prior to July 1, 2024, please use the appropriate miscellaneous code.

Coding Reference Guide

HCP Code*	Description
J3263	Injection, toripalimab-tpzi, 1 mg

*Effective for dates of service on or after July 1, 2024.

Billable Units	Description
1 mg	LOQTORZI® (toripalimab-tpzi) billable units

NDC	Description
70114-0340-01	240 mg/6 mL (40 mg/mL) single-dose vial (one carton)

CPT® Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

Some payers may prefer use of 96365. Check with the applicable payer.

Patient Diagnosis Code	Description
C11	Malignant neoplasm of nasopharynx
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified

ICD-10 codes vary by patient diagnosis

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

LOQTORZI (toripalimab-tpzi) is indicated:

- In combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or with recurrent, locally advanced nasopharyngeal carcinoma (NPC).
- As a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions listed herein may not include all possible severe and fatal immune-mediated adverse reactions. Immune-mediated adverse reactions, which can be severe or fatal, occur in any organ system or tissue, affect more than one body system simultaneously, and occur at any time after starting PD-1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment, they can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies.

Please see Important Safety Information throughout and Prescribing Information [here](#).

Coding Reference Guide

Modifier	Description
JG Modifier	Drug or biological acquired with 340B drug pricing program discount
JW Modifier	Drug amount discarded/not administered to any patient (indicate quantity discarded)
JZ Modifier	Zero drug amount discarded/not administered to any patient
TB Modifier	Drug or biological acquired with 340B drug pricing program discount; reported for informational purposes for select entities

Hospital Services and Supplies

Revenue Code	Description
0636	Drugs requiring detailed coding
0335	Chemotherapy administration, IV
0260	IV Therapy-General

For questions regarding LOQTORZI billing and coding, please call LOQTORZI Solutions™ at 1-844-483-3692 from 8 AM to 8 PM ET, Monday through Friday or visit LOQTORZISolutions.com.

The coding information contained herein is for informational purposes only and is not a guarantee of coverage or reimbursement for any product or service. Please contact the payer to confirm appropriate billing information. This information is not intended to substitute for the physician's independent diagnosis or treatment of each patient.

LOQTORZI Solutions™ is part of the Coherus Solutions™ family of programs.

IMPORTANT SAFETY INFORMATION, CONT'D

Severe and Fatal Immune-Mediated Adverse Reactions, Cont'd

- Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue LOQTORZI based on severity and type of reaction (see Dosage and Administration in Prescribing Information). In general, If LOQTORZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

Immune-Mediated Pneumonitis

LOQTORZI can cause immune-mediated pneumonitis.

- In patients receiving LOQTORZI in combination with cisplatin and gemcitabine, immune-mediated pneumonitis occurred in 2.1% (3/146) of patients, including Grade 2 (1.4%) adverse reactions. Pneumonitis resolved in 67% (2/3) of these patients.
- In patients receiving LOQTORZI monotherapy, immune-mediated pneumonitis occurred in 2.6% (22/851) of patients, including fatal (0.2%), Grade 3 (0.7%), and Grade 2 (1.1%) adverse reactions. Systemic corticosteroids were required in 82% (18/22) of patients with pneumonitis. Pneumonitis led to permanent discontinuation of LOQTORZI in 1.2% (10/851) of patients. Pneumonitis resolved in 23% (5/22) of these patients.

Immune-Mediated Colitis

LOQTORZI can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. In patients receiving LOQTORZI monotherapy, immune-mediated colitis occurred in 0.4% (3/851) of patients, including Grade 3 (0.2%) and Grade 2 (0.1%) adverse reactions. Colitis resolved in all 3 patients.

Please see Important Safety Information throughout and Prescribing Information [here](#).

IMPORTANT SAFETY INFORMATION, CONT'D

Hepatotoxicity and Immune-Mediated Hepatitis

LOQTORZI can cause immune-mediated hepatitis.

- In patients receiving LOQTORZI in combination with cisplatin and gemcitabine, immune-mediated hepatitis occurred in 0.7% (1/146) of patients, which was a Grade 3 (0.7%) adverse reaction. The patient with immune-mediated hepatitis required systemic corticosteroids.
- In patients receiving LOQTORZI monotherapy, immune-mediated hepatitis occurred in 3.3% (28/851) of patients, including Grade 4 (0.8%), Grade 3 (2.1%), and Grade 2 (0.4%) adverse reactions. Hepatitis led to permanent discontinuation of LOQTORZI in 1.1% of patients and withholding of LOQTORZI in 0.8% of patients. Hepatitis resolved in 54% (15/28) of these patients.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

LOQTORZI can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold or permanently discontinue LOQTORZI depending on severity. In patients receiving LOQTORZI monotherapy, adrenal insufficiency occurred in 0.5% (4/851) of patients, including Grade 2 (0.4%) and Grade 1 (0.1%) adverse reactions. Systemic corticosteroids were required in 75% (3/4) of the patients with adrenal insufficiency. Adrenal insufficiency led to withholding of LOQTORZI in 0.1% (1/851) of patients. In the one patient in whom LOQTORZI was withheld, LOQTORZI was reinitiated after symptom improvement.

Hypophysitis

LOQTORZI can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effects such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue LOQTORZI depending on severity. In patients receiving LOQTORZI monotherapy, hypophysitis occurred in 0.4% (3/851) of patients receiving LOQTORZI, including Grade 3 (0.2%) and Grade 2 (0.1%) adverse reactions. All three patients received systemic corticosteroids. Hypophysitis led to permanent discontinuation of LOQTORZI in 0.1% (1/851) of patients and withholding of LOQTORZI in 0.1% (1/851) of patients. The one patient in whom LOQTORZI was withheld reinitiated LOQTORZI.

Thyroid Disorders

LOQTORZI can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue LOQTORZI depending on severity.

- In patients receiving LOQTORZI in combination with cisplatin and gemcitabine, thyroiditis occurred in 2.1% (3/146) of patients receiving LOQTORZI, including Grade 2 (1.4%). Three patients required thyroid hormone replacement therapy. Thyroiditis resolved in one of the 3 patients. Hyperthyroidism occurred in 1.4% (2/146) of patients receiving LOQTORZI in combination with cisplatin and gemcitabine. Hyperthyroidism resolved in these 2 patients. Hypothyroidism occurred in 30% (44/146) of patients receiving LOQTORZI in combination with cisplatin and gemcitabine, including Grade 2 (24%) and Grade 1 (6%). Eighty percent of the 44 patients required thyroid hormone replacement therapy. LOQTORZI was withheld in 2.1% (3/146) of the patients. Of the 3 patients in whom LOQTORZI was withheld, 2 patients reinitiated LOQTORZI.
- In patients receiving LOQTORZI monotherapy, thyroiditis occurred in 0.6% (5/851) patients receiving LOQTORZI, including Grade 2 (0.1%). Two of these 5 patients received systemic corticosteroids and 2 required thyroid hormone replacement therapy. Thyroiditis resolved in 2 of the 5 patients. Hyperthyroidism occurred in 7% (55/851) of patients receiving LOQTORZI, including Grade 2 (1.9%). Hyperthyroidism resolved in 85% (47/55) of the patients. Hypothyroidism occurred in 15% (128/851) of patients receiving LOQTORZI, including Grade 2 (8%). Sixty three percent of the 128 patients required thyroid hormone replacement therapy. LOQTORZI was withheld in 0.5% of patients. Of the 4 patients in whom LOQTORZI was withheld, 3 patients reinitiated LOQTORZI.

Please see Important Safety Information throughout and Prescribing Information [here](#).

IMPORTANT SAFETY INFORMATION, CONT'D

Immune-Mediated Endocrinopathies, Cont'd

Type 1 Diabetes Mellitus, which can present with Diabetic Ketoacidosis

Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue LOQTORZI depending on severity. In patients receiving LOQTORZI monotherapy, diabetes mellitus occurred in 0.9% (8/851) of patients receiving LOQTORZI, including Grade 4 (0.1%), Grade 3 (0.7%), and Grade 2 (0.1%). Diabetes mellitus led to permanent discontinuation in 0.4% of patients. Six of the 8 (75%) patients with diabetes mellitus required long-term insulin therapy.

Immune-Mediated Nephritis with Renal Dysfunction

LOQTORZI can cause immune-mediated nephritis.

- In patients receiving LOQTORZI in combination with cisplatin and gemcitabine, immune-mediated nephritis occurred in 0.7% (1/146) of patients receiving LOQTORZI. The one patient with immune-mediated nephritis (Grade 4) required systemic corticosteroids and nephritis led to discontinuation of LOQTORZI. Nephritis resolved in this patient.
- In patients receiving LOQTORZI monotherapy, immune-mediated nephritis occurred in 0.5% (4/851) of patients, including Grade 3 (0.5%) adverse reactions. Nephritis resolved in 75% (3/4) of these patients.

Immune-Mediated Dermatologic Adverse Reactions

LOQTORZI can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue LOQTORZI depending on severity.

- In patients receiving LOQTORZI in combination with cisplatin and gemcitabine, immune-mediated dermatologic adverse reactions occurred in 8% (12/146) of patients, including Grade 3 (3.4%) and Grade 2 (1.4%) adverse reactions. Systemic corticosteroids were required in 25% (3/12) of the patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions led to permanent discontinuation of LOQTORZI in 2.1% (3) of patients. Immune-mediated dermatologic adverse reactions resolved in 92% (11/12) of these patients.
- In patients receiving LOQTORZI monotherapy, immune-mediated dermatologic adverse reactions occurred in 4% (34/851) of patients, including Grade 3 (0.4%) and Grade 2 (1.4%) adverse reactions. Immune-mediated dermatologic adverse reactions led to withholding of LOQTORZI in 0.4% (3) of the patients. Systemic corticosteroids were required in 12% (4/34) of the patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions resolved in 71% (24/34) of these patients.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received LOQTORZI or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

- *Cardiac/Vascular:* Myocarditis, pericarditis, vasculitis, pericardial effusion
- *Nervous System:* Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy
- *Ocular:* Uveitis, iritis and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.
- *Gastrointestinal:* Pancreatitis, to include increases in serum amylase and lipase levels, gastritis, duodenitis
- *Musculoskeletal and Connective Tissue:* Myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis, polymyalgia rheumatica, dermatomyositis
- *Endocrine:* Hypoparathyroidism

Please see Important Safety Information throughout and Prescribing Information [here](#).

IMPORTANT SAFETY INFORMATION, CONT'D

Other Immune-Mediated Adverse Reactions, Cont'd

- *Hematologic/Immune:* Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection

Infusion-Related Reactions

LOQTORZI can cause severe or life-threatening infusion-related reactions including hypersensitivity and anaphylaxis.

- In patients receiving LOQTORZI in combination with cisplatin and gemcitabine, infusion-related reactions have been reported in 4.1% of patients, including Grade 2 (0.7%) reactions.
- In patients receiving LOQTORZI monotherapy, infusion-related reactions occurred in 2% of 851 patients, including Grade 3 (0.1%) and Grade 2 (0.6%). LOQTORZI was withheld for one Grade 3 infusion related reaction. Monitor patients for signs and symptoms of infusion-related reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. Interrupt or slow the rate of infusion for mild (Grade 1) or moderate (Grade 2) infusion-related reactions. For severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions, stop infusion and permanently discontinue LOQTORZI.

Complications of Allogeneic Hematopoietic Stem Cell Transplant (HSCT)

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

LOQTORZI can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LOQTORZI and for 4 months after the last dose.

Lactation

There are no data on the presence of toripalimab-tpzi in human milk; its effects on the breastfed child, or on milk production. Maternal IgG is known to be present in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed child to toripalimab-tpzi are unknown. Because of the potential for serious adverse reactions in breastfed children, advise lactating women not to breastfeed during treatment with LOQTORZI and for 4 months after the last dose.

Serious Adverse Reactions

- In JUPITER-02, when LOQTORZI was administered in combination with cisplatin and gemcitabine for the first-line treatment of recurrent, locally advanced or metastatic nasopharyngeal carcinoma, serious adverse reactions occurred in 43% of patients. Serious adverse drug reactions in $\geq 2\%$ were thrombocytopenia (14%), neutrophil count decreased (10%), pneumonia (10%), anemia (9%), abnormal hepatic function (2.7%), and rash (2.1%). There were three fatal adverse reactions (2.1%): one due to epistaxis; one due to intracranial hemorrhage associated with immune-related thrombocytopenia and coagulopathy; and one due to pneumonia. Permanent discontinuation of LOQTORZI, due to an adverse reaction occurred in 12% of patients. Adverse reactions resulting in permanent discontinuation of LOQTORZI in $\geq 1\%$ were pneumonia (2.1%), pulmonary tuberculosis (1.4%), rash (1.4%), and vomiting (1.4%). The most common Grade 3 to 4 laboratory abnormalities ($\geq 2\%$) were decreased neutrophils (58%), decreased lymphocytes (57%), decreased hemoglobin (50%) decreased platelets (33%), decreased potassium (10%), decreased sodium (9%), increased alanine aminotransferase (6%), increased or decreased magnesium (4.2% each), decreased calcium (3.5%), increased aspartate aminotransferase (2.7%), and increased bilirubin (2.1%).

Please see Important Safety Information throughout and Prescribing Information [here](#).

IMPORTANT SAFETY INFORMATION, CONT'D

Serious Adverse Reactions, Cont'd

- In POLARIS-02, when LOQTORZI was administered as a single agent to patients with previously treated, unresectable or metastatic nasopharyngeal carcinoma, serious adverse reactions occurred in 24% of patients. Serious adverse drug reactions in $\geq 2\%$ were pneumonia (4.7%), abnormal hepatic function (2.6%), and hyperbilirubinemia (2.1%). Fatal adverse reactions occurred in 3.7% of patients who received LOQTORZI, including death not otherwise specified (1.6%), tumor hemorrhage (0.5%), hepatic failure and thrombocytopenia (0.5%), hyponatremia (0.5%), and sudden death (0.5%). Permanent discontinuation of LOQTORZI due to an adverse reaction occurred in 9% of patients. Adverse reaction resulting in permanent discontinuation of LOQTORZI in $\geq 1\%$ included pneumonia (1.1%), abnormal hepatic function (1.1%), and hyperbilirubinemia (1.1%). The most common Grade 3 or 4 laboratory abnormalities ($\geq 2\%$), were decreased sodium (11%), decreased lymphocytes (9%), decreased hemoglobin (6%), increased aspartate aminotransferase (3.8%), decreased phosphate (3.2%), and increased alkaline phosphatase (2.2%).

Common Adverse Reactions

- In JUPITER-02, the most common adverse reactions ($\geq 20\%$) were nausea (71%), vomiting (68%), decreased appetite (55%), constipation (39%), hypothyroidism (38%), rash (36%), pyrexia (32%), diarrhea (31%), peripheral neuropathy (30%), cough (26%), musculoskeletal pain (25%), upper respiratory infection (23%), insomnia (23%), dizziness (21%), and malaise (21%).
- In POLARIS-02, in patients with previously treated, unresectable or metastatic nasopharyngeal carcinoma, the most common ($\geq 20\%$) adverse reactions were hypothyroidism (27%), fatigue (22%), and cough (20%).

LOQTORZI[®] Injection: 240 mg/6 mL (40 mg/mL) solution in a single-dose vial

Please see Prescribing Information for [LOQTORZI](#).