Part B Prior Authorization Guidelines

Loqtorzi

Loqtorzi (toripalimab-tpzi) J2363

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Patient has a diagnosis of nasopharyngeal carcinoma (NPC); AND
☐ Individual is using in one of the following ways:
- ☐ Individual has metastatic or recurrent, locally advanced NPC; AND
- ☐ Individual is using in combination with cisplatin and gemcitabine; AND
- ☐ Individual is using as first-line treatment; AND
- ☐ Individual will use until disease progression, unacceptable toxicity, or up to 24 months;

OR
- ☐ Individual has recurrent, unresectable, or metastatic NPC with disease progression on or after platinum containing chemotherapy; AND
- ☐ Individual is using as a single agent;

☐ Patient has a current ECOG performance status of 0-1; AND
☐ Patient has not received treatment with another anti-PD-1 or anti-PD-L1 agent; AND
☐ Patient is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ **Continuation Requests: (Clinical documentation required for all requests)**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Loqtorzi PA

Drug Name(s):

LOQTORZI **TORIPALIMAB-TPZI**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Initial approval will be for 6 months. Continuation may be approved for up to 12 months.

FDA Indications:

Loqtorzi

- Nasopharyngeal carcinoma, Metastatic or recurrent locally advanced disease; first-line treatment in combination with CISplatin and gemcitabine
- Nasopharyngeal carcinoma, Recurrent unresectable or metastatic disease; progression on or after platinum-containing chemotherapy, single agent

Off-Label Uses:

- Non-small cell lung cancer, Advanced disease, first-line therapy in combination with platinum-containing doublet chemotherapy followed by toripalimab maintenance therapy (with pemetrexed for nonsquamous cell disease)
- Non-small cell lung cancer, Neoadjuvant therapy in combination with platinum-containing doublet chemotherapy, followed by one adjuvant cycle with combination therapy, then continued as single-agent maintenance therapy

Age Restrictions:

Safety and effectiveness have not been established in pediatric patients

Other Clinical Considerations:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=topHome&isToolPage=true#