10/14/2024

Prior Authorization Criteria for Imdelltra Effective Nov. 1, 2024

Background:

On Oct. 1, 2024, Imdelltra became a benefit of Medicaid and CHIP. HHSC requires prior authorization for Imdelltra (procedure code C9170) for Medicaid and CHIP, effective for dates of service on or after Nov. 1, 2024.

Key Details:

Imdelltra (Tarlatamab-dlle) is a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager indicated for the treatment of adult clients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

Imdelltra (Tarlatamab-dlle) infusion must be administered by a qualified healthcare professional in a health care setting with appropriate medical support.

HHSC requires prior authorization for Imdelltra (Tarlatamab-dlle) for clients who meet all the following requirements:

- · The client is 18 years or older.
- The client has a confirmed diagnosis of ES-SCLC (diagnosis code C3400, C3401, C3402, C3410, C3411, C3412, C342, C3430, C3431, C3432, C3480, C3481, C3482, C3490, C3491, or C3492).
- · The client has previously received platinum-based chemotherapy (cisplatin or carboplatin).
- · The client does not have a clinically significant active systemic infection.
- · The prescriber attests to counseling female clients of childbearing age regarding the risk of embryo-fetal toxicity and counseling to prevent pregnancy during the treatment period and two months after the last infusion of tarlatamab-dlle (Imdelltra) by using an effective method of contraception.

Providers should monitor the client for signs and symptoms of:

- · Severe reactions such as cytokine release syndrome (CRS).
- · Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).
- · Cytopenia, including neutropenia, thrombocytopenia, and anemia. Providers should perform complete blood counts before each tarlatamab-dlle (Imdelltra) treatment.
- · Hepatoxicity. Providers should monitor liver enzymes and bilirubin before each tarlatamabdlle (Imdelltra) treatment.

Requests for Renewal or Continuation of Therapy

The client must meet the following requirements to renew or continue with tarlatamab-dlle (Imdelltra) therapy:

- · The client continues to meet the requirements listed above and has been treated with tarlatamab-dlle (Imdelltra) in the past.
- · The client experienced positive clinical response to treatment, as documented by stabilization of the disease, and a decrease in tumor size or spread.
- · The client has not experienced any unacceptable, clinically significant adverse reactions or toxicity (severe cytopenia, hepatotoxicity, or neurotoxicity) while on tarlatamab-dlle (Imdelltra) therapy.

Additional Information:

Refer to the <u>Outpatient Drug Services Handbook Chapter</u> of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

HHSC approved this updated clinical prior authorization for use by MCOs, and will implement criteria for fee-for-service Medicaid on Nov. 1, 2024. MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but shall not make them more restrictive.

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