How to prepare IMDELLTRA® (tarlatamab-dlle)

Quick reference guide for pharmacists

IMDELLTRA® package

The **1 mg** package (NDC 55513-059-01) contains 1 single-dose vial of 1 mg of IMDELLTRA® and 2 vials of 7 mL IV Solution Stabilizer (IVSS)[1]

The **10 mg** package (NDC 55513-077-01) contains 1 single-dose vial of 10 mg of IMDELLTRA® and 2 vials of 7 mL IVSS[1]

IMDELLTRA® J-Code J9026, Injection, tarlatamab-dlle, 1 mg[2,*]

*The HCPCS billing unit for J9026 is 1 mg. J9026 can be used for both 1 mg and 10 mg IMDELLTRA® vials. It is the responsibility of the provider to report the number of billing units administered.

Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. This information is not a guarantee of coverage or reimbursement.

HCPCS, Healthcare Common Procedure Coding System; IV, intravenous; NDC, National Drug Code.

Please see the full Prescribing Information for additional information on Dosing and Administration.

INDICATION

IMDELLTRA® (tarlatamab-dlle) is indicated for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving IMDELLTRA®. Initiate treatment with IMDELLTRA® using the step-up dosing schedule to reduce the incidence and severity of CRS. Withhold IMDELLTRA® until CRS resolves or permanently discontinue based on severity.**
- **Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including serious or life-threatening reactions, can occur in patients receiving IMDELLTRA®. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment and treat promptly. Withhold IMDELLTRA® until ICANS resolves or permanently discontinue based on severity.**

Please see additional Important Safety Information, including BOXED WARNINGS, throughout.

IMDELLTRA® (tarlatamab-dlle) for injection 1 mg & 10 mg single-use vials

Preparing IMDELLTRA®

Step 1: Reconstitute IMDELLTRA® vial with Sterile Water for Injection

1. Using a needle and syringe filled with the required amount of sterile water (1.3 mL for 1 mg dose and 4.4 mL for 10 mg dose), inject the sterile water against the glass vial. Avoid injecting the water directly onto the powder to prevent foaming[1]
   - **Do not use IVSS for reconstitution of IMDELLTRA®**. The IVSS is used to coat the IV bag prior to addition of reconstituted IMDELLTRA® to prevent adsorption of IMDELLTRA® to IV bags and IV tubing[1]

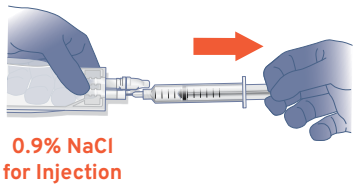
Please see the full Prescribing Information for additional information regarding the required amount of sterile water for reconstitution.

2. Gently swirl the contents to mix. Do not shake[1]

3. Inspect parenteral drug products for particulate matter and discoloration prior to administration. Inspect that the solution is clear to opalescent, colorless to slightly yellow. Do not use if the solution is cloudy or has particulates[1]

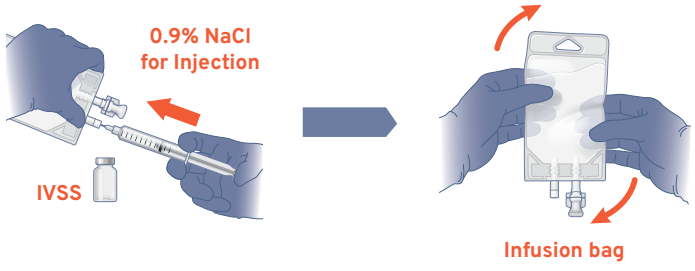
4. Further dilute reconstituted IMDELLTRA®[1]
5. The reconstituted IMDELLTRA® must be further diluted within 4 hours of reconstitution or discarded[1]

Step 2: Withdraw 0.9% Sodium Chloride for Injection



1. Using a 250 mL prefilled bag of 0.9% Sodium Chloride for Injection, **withdraw 14 mL** (for 1 mg IMDELLTRA® dose) **or 17 mL** (for 10 mg IMDELLTRA® dose) and discard[1]

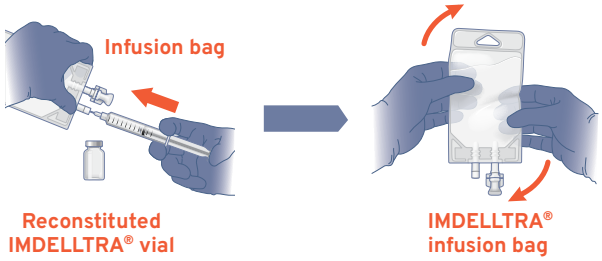
Step 3: Add IVSS to the infusion bag



1. Inject **13 mL of IVSS** into the 250 mL 0.9% Sodium Chloride infusion bag[1]
2. Gently mix the contents of the infusion bag to avoid foaming. Do not shake[1]

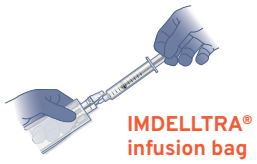
IV, intravenous; IVSS, intravenous solution stabilizer.

Step 4: Dilute the reconstituted IMDELLTRA® into the infusion bag



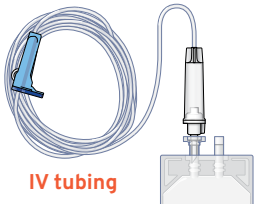
1. Transfer **1.1 mL** (for 1 mg IMDELLTRA® dose) **or 4.2 mL** (for 10 mg IMDELLTRA® dose) of reconstituted IMDELLTRA® to the infusion bag containing IVSS[1]
   - **NOTE:** the final concentrations for the different strength vials are NOT the same following reconstitution and further dilution[1]
2. Gently mix the contents of the bag. Do not shake[1]

Step 5: Remove air from the IV bag



1. Remove air from the prepared IV bag using an empty syringe to avoid foaming[1]

Step 6: Prime IV tubing



1. Prime IV tubing with either **0.9% Sodium Chloride for Injection or** with the **final prepared product**[1]
2. If the prepared IMDELLTRA® infusion bag is not used immediately, it can be stored at room temperature (20°C to 25°C or 68°F to 77°F) for 8 hours, or it can be refrigerated (2°C to 8°C or 36°F to 46°F) for 7 days[1]
   - Discard IMDELLTRA® infusion after maximum storage time (from time of reconstitution)[1]
   - Do not re-refrigerate the prepared infusion bag[1]

It is very important that the instructions for Dosing and Administration provided in the full Prescribing Information are strictly followed.

Please see the full Prescribing Information for additional information on Dosing and Administration.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Cytokine Release Syndrome (CRS):** IMDELLTRA® can cause CRS including serious or life-threatening reactions. In the pooled safety population, CRS occurred in 55% of patients who received IMDELLTRA®, including 34% Grade 1, 19% Grade 2, 1.1% Grade 3 and 0.5% Grade 4. Recurrent CRS occurred in 24% of patients, including 18% Grade 1 and 6% Grade 2.

  Most events (43%) of CRS occurred after the first dose, with 29% of patients experiencing any grade CRS after the second dose and 9% of patients experiencing CRS following the third dose or later. Following the Day 1, Day 8, and Day 15 infusions, 16%, 4.3% and 2.1% of patients experienced ≥ Grade 2 CRS, respectively.
  The median time to onset of all grade CRS from most recent dose of IMDELLTRA® was 13.5 hours (range: 1 to 268 hours). The median time to onset of ≥ Grade 2 CRS from most recent dose of IMDELLTRA® was 14.6 hours (range: 2 to 566 hours).

IMDELLTRA® (tarlatamab-dlle) for injection 1 mg & 10 mg single-use vials

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONT'D)

Clinical signs and symptoms of CRS included pyrexia, hypotension, fatigue, tachycardia, headache, hypoxia, nausea, and vomiting. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

Administer IMDELLTRA® following the recommended step-up dosing and administer concomitant medications before and after Cycle 1 IMDELLTRA® infusions as described in Table 3 of the Prescribing Information (PI) to reduce the risk of CRS. Administer IMDELLTRA® in an appropriate health care facility equipped to monitor and manage CRS. Ensure patients are well hydrated prior to administration of IMDELLTRA®.

Closely monitor patients for signs and symptoms of CRS during treatment with IMDELLTRA®. At the first sign of CRS, immediately discontinue IMDELLTRA® infusion, evaluate the patient for hospitalization and institute supportive care based on severity. Withhold or permanently discontinue IMDELLTRA® based on severity. Counsel patients to seek medical attention should signs or symptoms of CRS occur.

- **Neurologic Toxicity, Including ICANS:** IMDELLTRA® can cause serious or life-threatening neurologic toxicity, including ICANS. In the pooled safety population, neurologic toxicity, including ICANS, occurred in 47% of patients who received IMDELLTRA®, including 10% Grade 3. The most frequent neurologic toxicities were headache (14%), peripheral neuropathy (7%), dizziness (7%), insomnia (6%), muscular weakness (3.7%), delirium (2.1%), syncope (1.6%), and neurotoxicity (1.1%).

ICANS occurred in 9% of IMDELLTRA®-treated patients. Recurrent ICANS occurred in 1.6% of patients. Most patients experienced ICANS following Cycle 2 Day 1 (24%). Following Day 1, Day 8, and Day 15 infusions, 0.5%, 0.5% and 3.7% of patients experienced ≥ Grade 2 ICANS, respectively. The median time to onset of ICANS from the first dose of IMDELLTRA® was 29.5 days (range: 1 to 154 days). ICANS can occur several weeks following administration of IMDELLTRA®. The median time to resolution of ICANS was 33 days (range: 1 to 93 days).

The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

Patients receiving IMDELLTRA® are at risk of neurologic adverse reactions and ICANS resulting in depressed level of consciousness. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, in the event of any neurologic symptoms until they resolve.

Closely monitor patients for signs and symptoms of neurologic toxicity and ICANS during treatment. At the first sign of ICANS, immediately evaluate the patient and provide supportive therapy based on severity. Withhold IMDELLTRA® or permanently discontinue based on severity.

Please see IMDELLTRA® full Prescribing Information, including BOXED WARNINGS.

See the Dosing, Administration & Pharmacy Guide on IMDELLTRAhcp.com

Learn more about IMDELLTRA® at IMDELLTRAhcp.com

References: 1. IMDELLTRA® (tarlatamab-dlle) prescribing information, Amgen. **2.** Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-3-2024-drugs-and-biologicals.pdf. Accessed October 21, 2024.

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