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| Document Type: Subtype | Technical Document:Investigational Product Preparation Procedure |
| Title: | Investigational Product Preparation and Administration Instructions for Subcutaneous Administration of Teclistamab (JNJ-64007957) for Managed Access Programs |

# INVESTIGATIONAL PRODUCT PREPARATION AND ADMINISTRATION INSTRUCTIONS FOR SUBCUTANEOUS ADMINISTRATION OF TECLISTAMAB (JNJ-64007957) for Managed Access Programs

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## 1.0 INTRODUCTION

This Investigational Product Preparation and Administration Instruction (IPPI) provides instructions for preparation and administration of the investigational product (IP) Teclistamab (JNJ-64007957) for the Managed Access Programs. The IPPI must be carefully reviewed and strictly followed when preparing and administering the IP.

Any individual involved in the preparation and administration of the IP must follow their local guidelines to perform his/her activities.

## 2.0 DEFINITIONS AND ACRONYMS

| | |
|---|---|
| Baseline | Weight collected at the time closest to, but prior to, the start of study drug administration |
| Administration | Delivering the IP to the patient |
| CSTD | Closed System Transfer Device |
| Dispensing | Preparing and delivering the IP to the administration area |
| IP | Investigational Product (Teclistamab, JNJ-64007957) |
| IPPI | Investigational Product Preparation and Administration Instruction |

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# 3.0 PREPARATION OF THE INVESTIGATIONAL PRODUCT

## 3.1 IMPORTANT INFORMATION ABOUT JNJ-64007957

Teclistamab (JNJ-64007957) is supplied as **two (2) different IP vial concentrations and two (2) different IP vial presentations.**

**Table 1. Presentations of Teclistamab (JNJ-64007957) vials**

| When to use IP vial | IP Concentration (mg/mL) | IP Strength (mg) | Extractable Volume (mL) | Vial Presentation | Storage Conditions |
|---|---|---|---|---|---|
| For **60 mcg/kg** and **300 mcg/kg Priming** doses | **10 mg/mL** | **30 mg** | **3.0 mL** | Glass vial with a **BLUE** flip top cap | **Refrigerated** between 2°C to 8°C |
| For **1500 mcg/kg Treatment** doses | **90 mg/mL** | **150 mg** | **1.7 mL** | Glass vial with an **ORANGE** flip top cap | **Refrigerated** between 2°C to 8°C |

- Ensure the **correct IP vial concentration** is used during preparation and administration **according to the dose (60, 300, or 1500 mcg/kg).**

- Teclistamab (JNJ-64007957) must be protected from light during storage. Keep the vials in their original package until dose preparation. Protection from light is not required during equilibration, dose preparation, or administration.

- Teclistamab (JNJ-64007957) is supplied in a single-dose vial closed with elastomer stopper and aluminum seal with plastic flip off cap and can be used for only one preparation.

- Teclistamab (JNJ-64007957) should be visually inspected prior to use. IP solution in vial should be colorless to light yellow and free of visible particulate matter or ice. If the vial is cracked or if the IP solution is discolored, cloudy, or if any visible particulate matter is present do not use and contact the Janssen Managed Access Team (JanssenMAc@its.jnj.com).

- Dosing must occur within **4 hours** from the first IP vial puncture.

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## 3.2 MATERIALS AND EQUIPMENT

Description of materials required for preparation and admnistration of IP are noted in Table 2 below.

| Category | Product | Quantity for Unit* Operation |
|---|---|---|
| **Investigational Product** | **For 60 and 300 mcg/kg dose:** Teclistamab (JNJ-64007957) **10 mg/mL** (30 mg, 3.0 mL/vial extractable volume) | 1-2 |
| **Investigational Product** | **For 1500 mcg/kg dose:** Teclistamab (JNJ-64007957) **90 mg/mL** (150 mg, 1.7 mL/vial extractable volume) | 1-2 |
| **Ancillary Supplies** | Appropriately sized (1-mL to 3-mL) polypropylene and/or polycarbonate syringes with appropriate scale graduation | 1-3 |
| | For Preparation of IP: 21 – 27G needle | 1-3 |
| | For Administration of IP: 25 – 31G needle, 8 – 16 mm in length | 1-3 |
| | Syringe tip cap (any material of construction) | 1-3** |

**IP vial concentration, number of IP vial(s), syringe and needle size and quantity required will vary depending on total dose as detailed in Attachment 1, Table 3A, Table 3B and Table 4.*
***If the prepared syringe(s) is/are dispensed without integrated or attached needle(s)*

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### 3.2.1 CLOSED SYSTEM TRANSFER DEVICE

For transfer or dose volumes less than 1 mL, CSTDs must NOT be used for dose preparation or administration.

Commercially available CSTD's can be used in the preparation and administration of the IP for transfer and dose volumes more than or equal to 1 mL.

- The holdup volumes of the CSTD components (e.g., vial spike and syringe adapter) must be accounted for when drawing up the dose as this may impact the number of IP vials required to prepare the dose.

- For dose administration, holdup volumes of the CSTD must be accounted for during the preparation of the syringe(s) to ensure that the exact dose volume is in the syringe post priming the CSTD.

## 3.3 PREPARING DISPENSING LABEL

The site is responsible for creating dispensing labels(s) in accordance with the site procedures, and local regulatory requirements.

The following items are suggested on each IP Dispensing label:

1. Program No:
2. Patient No:
3. Total Dose: Teclistamab ____ mg* in ___ mL
4. Syringe #__ of __
5. This syringe contains _____mL
6. Store at room/ambient temperature
7. Administer Subcutaneously
8. Administer the entire contents of the syringe
9. Expiry**:
    - **Preferred format: dd / mon / yyyy HH : MM**

**Site may express dose in micrograms (mcg) per site procedures.*
***** Expiration time is 4 hours after the first IP vial is punctured.***

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## 3.4 DETERMINATION OF TOTAL DOSE VOLUME AND TOTAL DOSE/DOSE TABLE

The concentration of the IP vial to use and the dose volume of Teclistamab (JNJ-64007957) in **milliliters (mL)** is based on the **dose in micrograms per kilogram (mcg/kg)** prescribed in the treatment guidance and the **patient's body weight in kilograms (kg)**. All priming and treatment doses of Teclistamab should be based on baseline body weight using the appropriate dosing tables in this IPPI or direct calculation. However, if site procedures require using more recent weights (e.g. day of dosing weight) or if there is a significant change in body weight (>10% from baseline), the dose may be re-determined based on either the dosing table or dose calculation if the physician deems it appropriate.

Use **Attachment 1, Table 3A: Teclistamab (JNJ-64007957) Dosing Table for 60 mcg/kg and 300 mcg/kg priming doses** to determine the total dose volume (mL) and total dose (mg) by patient's body weight (kg).

Use **Attachment 1, Table 3B: Teclistamab (JNJ-64007957) Dosing Table for 1500 mcg/kg treatment doses** to determine the total dose volume (mL) and total dose (mg) by patient's body weight (kg).

## 3.5 NUMBER OF IP VIALS REQUIRED PER DOSE

The total number of IP vials required to prepare each dose is based upon the dose (60, 300, or 1500 mcg/kg) and patient's body weight.

Use **Attachment 1, Table 4: Teclistamab (JNJ-64007957) Vials Required per Dose and Patient Body Weight** to determine the concentration and the number of IP vial(s) to use for each dose.

## 3.6 PREPARATION STEPS

Step by step instructions for preparing the IPs are provided in **Attachment 2**. All preparation steps must be followed in the specified order with documentation of critical steps (e.g. total volume of IP withdrawn).

- IP preparation **MUST BE** performed using aseptic technique. It is prefered that the preparation is performed under a laminar flow hood or biosafety cabinet.
- Injection volumes per syringe can be determined by site practice with the following guidelines:
    - Per site procedures, a subcutaneous injection dose volume ≤ 1 mL may be split between two 1-mL syringes.
    - A 2 to 3-mL syringe may be used for subcutaneous injection volumes greater than 1 mL.

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  - Each injection cannot exceed 2 mL in volume. It is preferable to split total injection volumes evenly between syringes.

- Ensure hold up volume in the needle(s) and needle hub(s) are fully accounted during the preparation procedure, especially for dosing volumes < 1 mL

- All used vials and any material remaining in a vial after preparation should be discarded per local/site/pharmacy procedures. This material should not be re-stored/used for future dose preparation on subsequent days.

## 4.0 **ADMINISTRATION**

The Investigational Product Dose Administration Procedures are provided in **Attachment 3**, which is provided directly to the Dose Administrator as a stand-alone document.

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**ATTACHMENT 1: TECLISTAMAB (JNJ-64007957) DOSING TABLES, NUMBER OF IP VIALS REQUIRED PER DOSE (PAGE 1/4)**

**Table 3A: Teclistamab (JNJ-64007957) Dosing Table for 60 mcg/kg and 300 mcg/kg Priming Doses[1]**

| | 10mg/mL (30 mg) IP Vial | | | |
|---|---|---|---|---|
| **Patient Body weight[2,3]** | Dose: **60 mcg/kg** | | Dose: **300 mcg/kg** | |
| | **Total Dose Volume** | **Total Dose** | **Total Dose Volume** | **Total Dose** |
| 35-39 kg | 0.22 mL | 2.2 mg | 1.1 mL | 11 mg |
| 40-44 kg | 0.25 mL | 2.5 mg | 1.3 mL | 13 mg |
| 45-49 kg | 0.28 mL | 2.8 mg | 1.4 mL | 14 mg |
| 50-59 kg | 0.33 mL | 3.3 mg | 1.6 mL | 16 mg |
| 60-69 kg | 0.39 mL | 3.9 mg | 1.9 mL | 19 mg |
| 70-79 kg | 0.45 mL | 4.5 mg | 2.2 mL | 22 mg |
| 80-89 kg | 0.51 mL | 5.1 mg | 2.5 mL | 25 mg |
| 90-99 kg | 0.57 mL | 5.7 mg | 2.8 mL | 28 mg |
| 100-109 kg | 0.63 mL | 6.3 mg | 3.1 mL | 31 mg |
| 110-119 kg | 0.69 mL | 6.9 mg | 3.4 mL | 34 mg |
| 120-129 kg | 0.75 mL | 7.5 mg | 3.7 mL | 37 mg |
| 130-139 kg | 0.81 mL | 8.1 mg | 4.0 mL | 40 mg |
| 140-149 kg | 0.87 mL | 8.7 mg | 4.3 mL | 43 mg |
| 150-160 kg | 0.93 mL | 9.3 mg | 4.7 mL | 47 mg |

*[1] This table based on body weight ranges was prepared to provide a reference for consistent teclistamab priming dosing based on baseline body weight and the average priming dose for each range. Alternatively, sites may opt to calculate dose based on exact baseline body weights (or any point thereafter, as per the footnote below).*
*[2] All priming doses of teclistamab should be based on baseline body weight using the appropriate dosing tables in this IPPI or direct calculation. However, if site procedures require using more recent weights (e.g. day of dosing weight) or if there is a significant change in body weight (>10% from baseline), the priming dose may be re-determined based on either the dosing table or dose calculation if the physician deems it appropriate.*
*[3] Standard rounding rules may be applied if allowed per site procedures.*

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**ATTACHMENT 1: Teclistamab (JNJ-64007957) Dosing Tables, Number of IP Vials Required Per Dose (Page 2/4)**

**Table 3B: Teclistamab (JNJ-64007957) Dosing Table for 1500 mcg/kg Treatment Doses[1]**

| | **90mg/mL (150mg) IP Vial** | |
|---|---|---|
| **Patient Body weight[2,3]** | Dose: **1500 mcg/kg** | |
| | **Total Dose Volume** | **Total Dose** |
| 35-39 kg | 0.62 mL | 56 mg |
| 40-44 kg | 0.70 mL | 63 mg |
| 45-49 kg | 0.78 mL | 70 mg |
| 50-59 kg | 0.91 mL | 82 mg |
| 60-69 kg | 1.1 mL | 99 mg |
| 70-79 kg | 1.2 mL | 108 mg |
| 80-89 kg | 1.4 mL | 126 mg |
| 90-99 kg | 1.6 mL | 144 mg |
| 100-109 kg | 1.7 mL | 153 mg |
| 110-119 kg | 1.9 mL | 171 mg |
| 120-129 kg | 2.1 mL | 189 mg |
| 130-139 kg | 2.2 mL | 198 mg |
| 140-149 kg | 2.4 mL | 216 mg |
| 150-160 kg | 2.6 mL | 234 mg |

*[1] This table based on body weight ranges was prepared to provide a reference for consistent teclistamab treatment dosing based on baseline body weight and the average treatment dose for each range. Alternatively, sites may opt to calculate dose based on exact baseline body weights (or any point thereafter, as per the footnote below).*

*[2] All treatment doses of teclistamab should be based on baseline body weight using the appropriate dosing tables in this IPPI or direct calculation. However, if site procedures require using more recent weights (e.g. day of dosing weight) or if there is a significant change in body weight (>10% from baseline), the treatment dose may be re-determined based on either the dosing table or dose calculation if the physician deems it appropriate.*

*[3] Standard rounding rules may be applied if allowed per site procedures.*

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**ATTACHMENT 1: TECLISTAMAB (JNJ-64007957) DOSING TABLES, NUMBER OF IP VIALS REQUIRED PER DOSE (PAGE 3/4)**

**Table 4: Teclistamab (JNJ-64007957) Vials Required per Dose and Patient Body Weight**

| | Use Teclistamab **10 mg/mL** (30 mg) IP | | Use Teclistamab **90 mg/mL** (150mg) IP |
|---|---|---|---|
| **Patient Body Weight[1]** | **Number of Vials to Use at 60 mcg/kg** | **Number of Vials to Use at 300 mcg/kg** | **Number of Vials to Use at 1500 mcg/kg** |
| 35-99 kg | 1 | 1 | 1 |
| 100-109 kg | 1 | 2 | 1* |
| 110-160 kg | 1 | 2 | 2 |

[1] *Standard rounding rules may be applied if allowed per site procedures.*

** By common practice, each 150 mg vial contains sufficient overfill to deliver the 153 mg dose (1.7 mL) for the 100-109 kg body weight category, thus necessitating the use of only 1 vial of the 90 mg/mL IP.*

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**ATTACHMENT 1: TECLISTAMAB (JNJ-64007957) DOSING TABLES, NUMBER OF IP VIALS REQUIRED PER DOSE (PAGE 4/4)**

The appearance of *representative* IP vials and labels are shown below. Exact IP label appearance may vary. **Ensure that Teclistamab and the proper concentration IP is selected** by checking the IP vial label.

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## ATTACHMENT 2: PREPARATION STEPS FOR TECLISTAMAB (JNJ-64007957)

| PREPARATION STEPS | |
|---|---|
| **1.** | Obtain the appropriate quantity of IP vial(s). Refer to Attachment 1, **Table 4: Teclistamab (JNJ-64007957) Vials required per Dose and Patient Body Weight.**<br><br>**Verify the IP vial and concentration** |
| **2.** | Remove the **10 mg/mL** or **90 mg/mL** IP vial(s) from the refrigerator and leave at room/ambient conditions for 15 minutes-4 hours before IP vial puncture. Do not use a water-bath or any other heat source.<br>Once equilibrated, gently swirl the IP vial(s) for approximately 10 seconds to mix before dose preparation. Do not shake. |
| **3.** | If the site preference is to dispense the syringe with an attached needle, follow steps 3A, 4 and 5.<br>If the site preference is to dispense the syringe with a syringe tip cap, follow steps 3B, 4 and 5. |
| **3A** | Using appropriately sized syringe(s) with attached needle(s) (as listed in Table 2), withdraw the total dose volume of IP based on dose and patient body weight as shown in:<br>For Priming Doses **60 mcg/kg and 300 mcg/kg**, use **Attachment 1, Table 3A**<br>OR<br>For Treatment Dose **1500 mcg/kg**, use **Attachment 1, Table 3B**<br><br>***Expiration time is 4 hours after the first IP vial is punctured.*** |
| **3B** | Using appropriately sized syringe(s) and needle(s) (as listed in Table 2), withdraw the total dose volume of IP based on dose and patient body weight as shown in:<br>For Priming Doses **60 mcg/kg and 300 mcg/kg**, use **Attachment 1, Table 3A**<br>OR<br>For Treatment Dose **1500 mcg/kg**, use **Attachment 1, Table 3B**<br>Ensure holdup volume in the needle(s) and needle hub(s) are fully accounted during the preparation procedure, especially for dosing volumes <1mL. Recommended procedure for accounting for holdup volumes: before removing needle from the syringe, pull back the syringe plunger slightly to empty the IP from the needle. Remove the needle, remove the air bubbles from the syringe, and apply the syringe tip cap.<br><br>***Expiration time is 4 hours after the first IP vial is punctured.*** |

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| **4.** | Apply the dispensing label(s) with expiration time of the product on the label for transport to administration area. |
| **5.** | All used vials and any material remaining in vial after preparation should be discarded per local/site/pharmacy procedures. **Do not re-use.** |
| **END OF ATTACHMENT 2** | |

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## ATTACHMENT 3: DOSE ADMINISTRATION PROCEDURES FOR TECLISTAMAB (JNJ-64007957)

Important Information about Teclistamab (JNJ-64007957) for subcutaneous administration:

- Administration of IP must be performed using aseptic technique.
- Do not shake the prepared dosing syringe.
- Store IP at room temperature and ambient light conditions until administration.
- For IP dose volumes more than or equal to 1 mL, CSTDs may be used for administration of the IP. Holdup volume of CSTD must be accounted for during the preparation of the syringe(s) to ensure that the exact dose volume is in the syringe(s) after priming the CSTD.

| **Subcutaneous Administration Steps** |
|---|
| **1**. Upon receipt of the IP syringe(s) in the administration area, the Dose Administrator must confirm all syringes are received (based on total dose). Depending on patient's dose, 1-3 labeled syringe(s) will be received containing IP. All the received IP syringes must be completely administered before expiration stated on the label of the syringe. |
| **2.** The IP syringe(s) for Subcutaneous injection may have an attached needle or may have a syringe tip cap. If IP syringe arrives with a syringe tip cap, the tip cap will be removed and must be replaced with one 25-31 G 8-16 mm needle. Check and verify the correct injection volume for each syringe and adjust carefully if necessary.<br><br>Administer the subcutaneous dose per site/local guidance and the following instructions: The preferred location for subcutaneous injection is the abdomen. An alternative injection site location such as the thigh or arm may be utilized if there are scars, tattoos, skin imperfections or if all locations of the abdomen were used for other subcutaneous injections. If a drug other than teclistamab is administered subcutaneously within 24 hours of teclistamab, then the injections should be administered in different anatomical locations (at least 10 cm apart). If multiple injections of teclistamab are performed within 24 hours (e.g. multiple syringes, interruption/resumption of dose), the teclistamab injections should be separated by approximately 2 cm or more. |
| **3.** Safely discard sharps per institutional guidelines. |
| **4.** Do not press or rub the Teclistamab (JNJ-64007957) site(s) of injection. |

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## 5.0 REVISION HISTORY

| Document Revision History | | | |
|---|---|---|---|
| **Version Number** | **Section** | **Description of Change** | **Justification of Change** |
| 3.0 | All | Changed “protocol” to “program”<br>Changed “subject” to “patient”<br>Changed “investigator” to “physician” | Clarification |
| 2.0 | All | Changed IP vial presentation from 144 mg (90 mg/mL) to 150 mg (90 mg/mL) | Label change |
| | All | Updated formatting to highlight IP concentrations instead of IP strengths | Clarification |
| | All | Relevant dosing and administration procedures/language updated to align with TV-TEC-180723.v.3.0 | Clarification |
| 1.0 | All | New document | New document |

Document Approvals

Approved Date:

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| Additional Approval Task<br>Verdict: Approve | Michael Zakrewsky,<br>(mzakrews@its.jnj.com)<br>Department Approval<br>22-Nov-2021 20:23:26 GMT+0000 |

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| Additional Approval Task<br>Verdict: Approve | Francis Meacle,<br>(fmeacle@its.jnj.com)<br>Department Approval<br>22-Nov-2021 20:26:13 GMT+0000 |

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| Mandatory Approval Task<br>Verdict: Approve | Tiffany Grace Pinkerton,<br>(TPinker1@its.jnj.com)<br>Document Management Approval<br>02-Dec-2021 14:56:22 GMT+0000 |