Clinical Trial Referral Report

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Trial Information

NCT ID: NCT05346835

Title: Intermediate-Size Population Expanded Access Program (EAP) for Ciltacabtagene Autoleucel (Cilta-cel) Out-of-Specification (OOS) in Patients With Multiple Myeloma

Status: MATCH

Patient Summary

Age: 79 | **Sex:** Female

Cancer Type: Multiple Myeloma

Stage:

ECOG: 0

Criteria Met (3)

✓ Cancer type 'Multiple Myeloma' matches 'Multiple Myeloma' (via disease target mapping)

✓ Age 79 >= 18

✓ diagnosis.cancer_type: 'Multiple Myeloma' matches ['multiple myeloma', 'myeloma', 'plasma cell myeloma', 'relapsed refractory multiple myeloma', 'plas

Requires Manual Review (4)

■ Eligible for treatment with cilta-cel per United States Prescribing Information (USPI)

■ Has serious or life-threatening multiple myeloma per USPI, and where re-apheresis, re-manufacturing, or other anti-myeloma directed therapy is not con

■ Favorable participant benefit/risk assessment determined by Janssen medical review

■ Treating physician confirms the favorable risk benefit profile, and that proceeding with this treatment is in the best interest of the participant

Procedural Criteria - Auto-Pass (2)

• Able to provide informed consent indicating they understand the purpose of this expanded access program (EAP)

• A woman of childbearing potential must have a negative highly sensitive serum (beta-human chorionic gonadotropin [beta-hCG]) pregnancy test during scr

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