Optum Rx®

CAR T cell therapy– FDA safety update

- On November 28, 2023, the FDA announced they are investigating the risk of serious risk of T-cell malignancy following BCMA-directed or CD19-directed autologous chimeric antigen receptor (CAR) T cell immunotherapies.

- The FDA has received reports of T-cell malignancies, including CAR-positive lymphoma, in patients who received treatment with BCMA- or CD19-directed autologous CAR T cell immunotherapies. Reports were received from clinical trials and/or postmarketing adverse event (AE) data sources.

- The FDA has determined that the risk of T-cell malignancies is applicable to all currently approved BCMA-directed and CD19-directed genetically modified autologous CAR T cell immunotherapies. T-cell malignancies have occurred in patients treated with several products in the class. Currently approved products in this class include the following:

    - Abecma® (idecabtagene vicleucel)
    - Breyanzi® (lisocabtagene maraleucel)
    - Carvykti® (ciltacabtagene autoleucel)
    - Kymriah® (tisagenlecleucel)
    - Tecartus® (brexucabtagene autoleucel)
    - Yescarta® (axicabtagene ciloleucel)

- Although the overall benefits of these products continue to outweigh their potential risks for their approved uses, the FDA is investigating the identified risk of T cell malignancy with serious outcomes, including hospitalization and death, and is evaluating the need for regulatory action.

- As with all gene therapy products with integrating vectors, the potential risk of developing secondary malignancies is labeled as a class warning in the prescribing information for approved BCMA-directed and CD19-directed genetically modified autologous T cell immunotherapies.

- Patients and clinical trial participants receiving treatment with these products should be monitored life-long for new malignancies.

    - If a new malignancy occurs following treatment with these products, the manufacturer should be contacted to report the event and obtain instructions on collection of patient samples for testing for the presence of the CAR transgene.

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