

## CBER Breakthrough Therapy Designation Requests Received by Fiscal Year

Cohort: October 1, 2023 - September 30, 2025

Data as of September 30, 2025

Fiscal Year	Total Requests Received	Granted	Denied	Withdrawn
2025	27	10	13	1

\* Requests that are still pending a decision are included in the total requests received column. Withdrawns are counted in received total.