



New Specialty Drug / Indication

POLICY

This policy addresses the management of newly approved specialty drug products or new indications by the United States Food & Drug Administration (FDA) that are used to treat chronic and complex diseases other than cancer and related disorders. It includes coverage requests for recently launched specialty drugs or recently updated indications where a guideline is in development but has not yet completed the required organizational and regulatory review processes.

For all such requests, clinical review will be conducted on a case-by-case basis to determine whether a specialty drug is considered medically necessary based upon the following criteria:

1. The drug is being requested for an FDA-approved indication, where the safety and effectiveness for the indication have been demonstrated by a well-designed clinical trial (i.e., Phase III or Phase IIb [single center]).
2. The member does not have any contraindication(s) to the requested specialty drug that are noted in the prescribing information.
3. All supporting laboratory or test results required in the prescribing information are provided, if applicable.
4. A specialty drug requested to be used in combination with other medications must not have contraindication(s) listed in the prescribing information regarding the combined use of those medications, if applicable.
5. The member has tried and failed other clinically appropriate therapy as noted in the prescribing information, if applicable.

Dosing recommendations for new specialty drug products or updated indications not covered by a specific eviCore clinical guideline will be determined by the FDA-approved dose for each indication as noted in the prescribing information.

This policy is not intended to limit eviCore's ability to manage any specialty drug product. Please refer to the specific health plan's individual benefit coverage provisions for additional management descriptions.