Cost Review: Selection of Therapeutic Alternatives

February 26, 2023

Prescription Drug Affordability Board Staff

MARYLAND
Prescription Drug Affordability Board

Agenda

- Overview of Therapeutic Alternatives in Cost Review
- Definitions Related to Therapeutic Alternatives
- Selection Process for Therapeutic Alternatives
- Example of Selection of Therapeutic Alternatives

Therapeutic Alternatives in Cost Reviews

§ 21-2C-09. Cost review of prescription drug products identified in § 21-2C-08

Factors to consider when conducting cost review

(b)(2) To the extent practicable, in determining whether a prescription drug product identified under § 21-2C-08 of this subtitle has led or will lead to an affordability challenge, the Board shall consider the following factors:

(iv) The price at which therapeutic alternatives have been sold in the State;

(v) The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefits managers in the State for therapeutic alternatives;

(ix) The relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;

Therapeutic Alternatives in Cost Reviews

COMAR 14.01.04.03 Selecting Drugs for Cost Review

H. Therapeutic Alternatives

(1) Board staff may develop a list of therapeutic alternatives for each prescription drug product referred to the Stakeholder Council.

(2) Board staff shall post a list of therapeutic alternatives developed by staff on the Board's website for comment.

(3) The public may provide written comments concerning the list of therapeutic alternatives by:

(a) Complying with the procedures in COMAR 14.01.01.05B(3); and

(b) Submitting the written comments to the Board within 30 calendar days of the date the list is posted on the Board's website.

(4) Board staff may modify the list of therapeutic alternatives for consideration by the Board. (5) The Board shall determine the therapeutic alternatives for each prescription drug product selected for a cost review study.

I. Board Selection of Drugs for Cost Review.

(8) If the Board selects a prescription drug product for cost review, the Board shall approve the therapeutic alternatives to be used in conducting the cost review study.

Therapeutic Alternatives in Cost Reviews

COMAR 14.01.04.05 Cost Review Study

C. Factors Considered in Cost Review Study

(1) To the extent practicable, the Board may consider the following data, information, and analyses in conducting a cost review study:

(c)Therapeutic Alternatives:

(i) The average price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans in the State for therapeutic alternatives; and

(ii) The WAC, AWP, NADAC, SAAC, ASP, and FSS at which each therapeutic alternative has been sold in the State;

Therapeutic Alternatives in Cost Reviews

COMAR 14.01.04.05 Cost Review Study

C. Factors Considered in Cost Review Study

(1) To the extent practicable, the Board may consider the following data, information, and analyses in conducting a cost review study:

(e) Cost and Comparative Effectiveness Analyses:

(i) The incremental costs associated with a prescription drug product including financial impacts to health, medical, or social services as can be quantified and compared to baseline effects of existing therapeutic alternatives; and

(ii) Information derived from health economics and outcomes research that may address the effectiveness of the prescription drug product in treating the conditions for which it is prescribed or in improving a patient's health, quality of life, or overall health outcomes, and the effectiveness of the prescription drug product compared with therapeutic alternatives or no treatment.

Therapeutic Alternatives- Definitions

COMAR 14.01.01.01.

Definitions

- “Therapeutic alternative” means a drug product that has the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug.
- “Therapeutic class” means a group of drugs containing active moieties that share scientifically documented properties and are defined on the basis of any combination of three attributes: mechanism of action, physiologic effect, and chemical structure.
- “Therapeutic equivalent” has the meaning stated in 21 CFR §314.3.

Timeline

Identify → **Select**

PDAB Meeting	PDAB Meeting	Stakeholder Council Meeting	Interim	PDAB Meeting
Public Reporting of Drug Affordability Issues Board has opportunity to add prescription drug products for inclusion on the list of eligible drugs for cost review	Identifying prescription drug products to consider for cost review- this is a subset from eligibility list Refer prescription drug products to the Stakeholder Council for input	PDASC will review and discuss the referred prescription drug products at an open meeting	Public comment Listening sessions	Board selects prescription drug product(s) for cost review Next Steps: ➔ Collect ➔ Analyze ➔ Results

Process for Selecting Therapeutic Alternatives

- Board staff may develop and post an initial draft list of therapeutic alternatives for each drug referred to Stakeholder Council
- Public may provide written comments regarding therapeutic alternatives
- Staff may modify the list of therapeutic alternatives for consideration by Board
- Board shall determine the therapeutic alternatives for each prescription drug product selected for cost review study

Stakeholder Council- Process for Selecting Therapeutic Alternatives

Publish Draft List of Therapeutic Alternatives	Public Comment	Approve Final List of Therapeutic Alternatives
The Board will publish a draft list of proposed therapeutic alternatives for each of the drugs that are referred to the Stakeholder Council	The public can provide written comment on the draft proposed therapeutic alternatives, including feedback on drugs on the proposed list that should not be considered therapeutic alternatives or drugs that should be on the list	The Board will publish proposed final list of therapeutic alternatives For each drug that the Board selects for Cost Review, Board will approve the final list of therapeutic alternatives

Key Considerations

- List of therapeutic alternatives should include all drugs that the Board wants to evaluate and compare when conducting the Cost Review study
- Over-inclusion of therapeutic alternatives is preferable to allow for the necessary nuance to consider multiple alternatives in the Cost Review Study

Example: Warfarin

- FDA Indications
    - Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism
    - Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement
    - Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction
- Guideline Summary
    - Venous thromboembolism: Anticoagulation after initial management
        - Vitamin K antagonist, Factor Xa Inhibitors, direct thrombin inhibitors, and LMWH

Example: List of Warfarin Therapeutic Alternatives

Chemical Name	Brand Name	Biosimilar/Generics?	Biosimilar Name	Therapeutic Class	Indication 1	Indication 2	Indication 3	Indication 4
Warfarin	Coumadin, Jantoven	Yes		Vit K Agonist	Venous Thrombosis	Pulmonary Embolism	Thromboembolic complications associated with atrial fibrillation	Thromboembolic event after MI
Rivaroxaban	Xarelto	No		Factor Xa Inhibitor	Stroke and systemic embolism in patients with nonvalvular atrial fibrillation			
Apixaban	Eliquis	No		Factor Xa Inhibitor	Stroke and systemic embolism in patients with nonvalvular atrial fibrillation			
Edoxaban	Savaysa	No		Factor Xa Inhibitor	Stroke and systemic embolism in patients with nonvalvular atrial fibrillation			
Dabigatran	Pradaxa	No		Director Thrombin Inhibitor	Reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation			
Enoxaparin Sodium	Lovenox	Yes	Clexane	Low molecular weight heparin	Prophylaxis of deep vein thrombosis	Prophylaxis of ischemic complications unstable angina	Acute ST-segment elevation myocardial infarction (STEMI)	
Fondaparinux	Arixtra	Yes		Factor Xa inhibitor through ATIII	Prophylaxis of deep vein thrombosis (DVT) in patients undergoing hip fracture surgery	Treatment of DVT or acute pulmonary embolism (PE) when administered in conjunction with warfarin		

Next Steps

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