Proposed Rule - Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce OOP Expenses

Avalere Health | An Inovalon Company
December 3, 2018

The Proposed Rule Included Content on 6 Key Topics

1 | **Plan Flexibility & Protected Classes**

2 | **E-Prescribing**

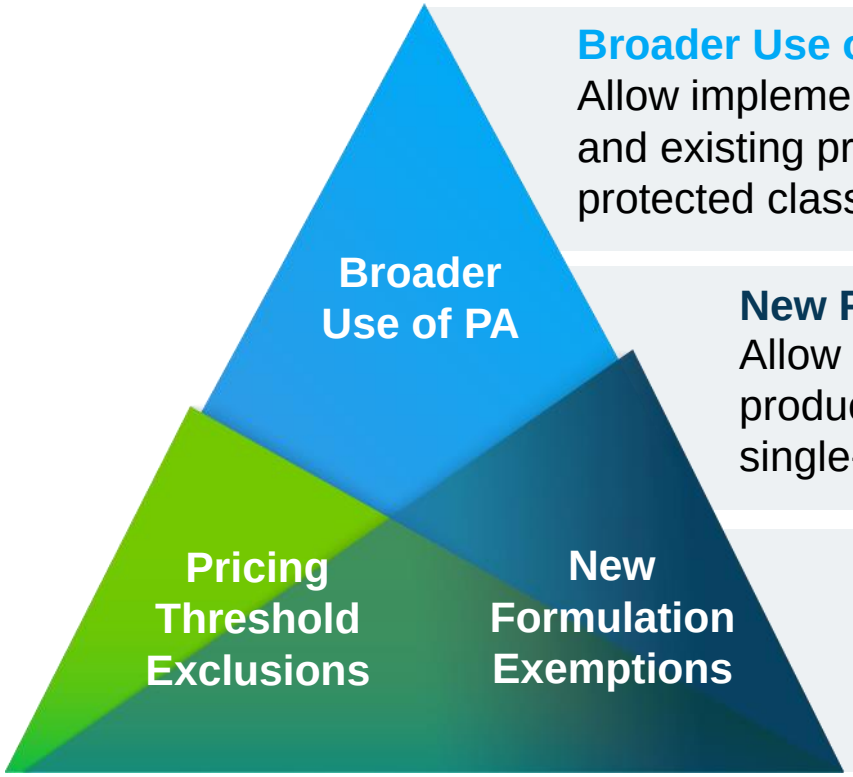
3 | **Use of Step Therapy for Part B Drugs**

4 | **Part D Explanation of Benefits**

5 | **Prohibition Against Gag Clauses in Pharmacy Contracts**

6 | **Pharmacy Concessions to Drug Prices at POS**

CMS Proposes Three Policy Changes That Would Impact Protected Class Drugs



Broader Use of Prior Authorization (PA)
Allow implementation of PA and step therapy for new start and existing prescriptions, including to determine use of protected class indication

New Formulation Exemptions
Allow exclusion of a protected class drug if the product is only a new formulation of an existing single-source drug or biological product

Pricing Threshold Exclusions
Allow exclusion of a protected class drug if its price growth exceeds a specified threshold

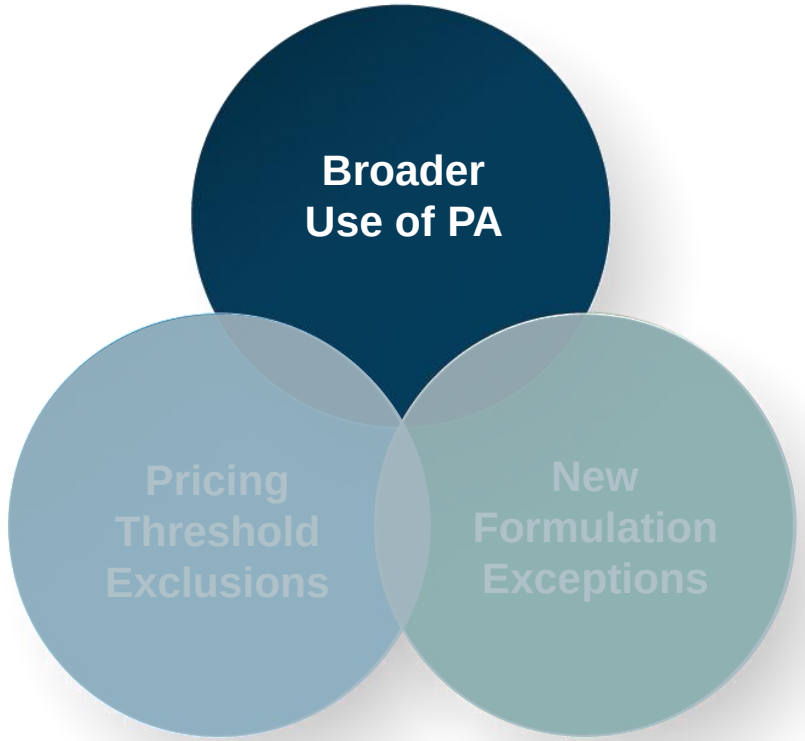
The proposed protected class exceptions could fundamentally change the Part D program and limit access for patients who use affected drugs

Broader Use of PA Could Impact Access to Current Treatments, Non-Protected Indications

Proposed Changes

Allow plan sponsors to:

- Use prior authorization or step therapy for any protected class drugs regardless of whether the beneficiary is just starting the treatment or already using the product
- Exclude (with CMS' permission) drugs from protected classes that are used by patients for non-protected indications

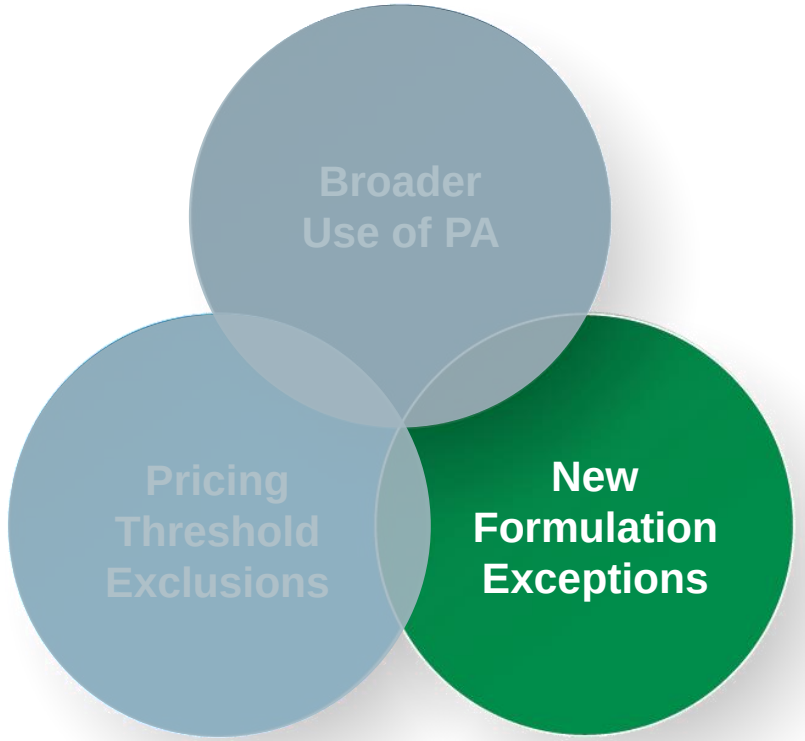


PA: Prior Authorization; CMS: Centers for Medicare & Medicaid Services

Formulation-Based Exceptions Could Limit Access to New Formulations of a Protected Class Product

Proposed Changes

- Allow Part D plans to exclude from their formularies a protected class single-source drug or biological product if the manufacturer launches a new formulation with the same active ingredient or moiety that does not provide a different route of administration
- Proposal would apply even if drug's older formulation was removed from market



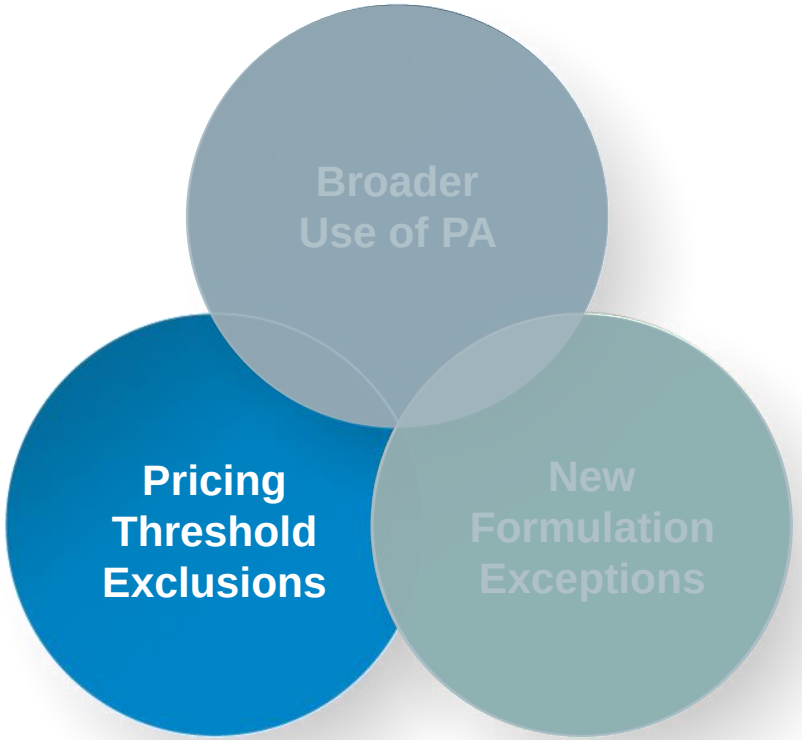
Price Growth Exclusion Could Apply to Most Protected Class Drugs

Proposed Changes

Allow exclusion of any single-source drug or biological product if its price increases beyond the rate of inflation

- Calculation would be based on WAC for pricing and CPI-U to calculate inflation
- If WAC increases faster than CPI-U during an applicable time period, CMS would allow that all NDCs* for that drug could be excluded from the formulary
- Plans would monitor pricing changes and decide on formulary exclusions, with oversight from CMS

CMS is considering allowing an affected protected class drug to be excluded from any future contract year



CMS: Centers for Medicare and Medicaid Services; WAC: Wholesale Acquisition Cost; CPI-U: Consumer Price Index for all Urban Consumers; NDC: National Drug Codes

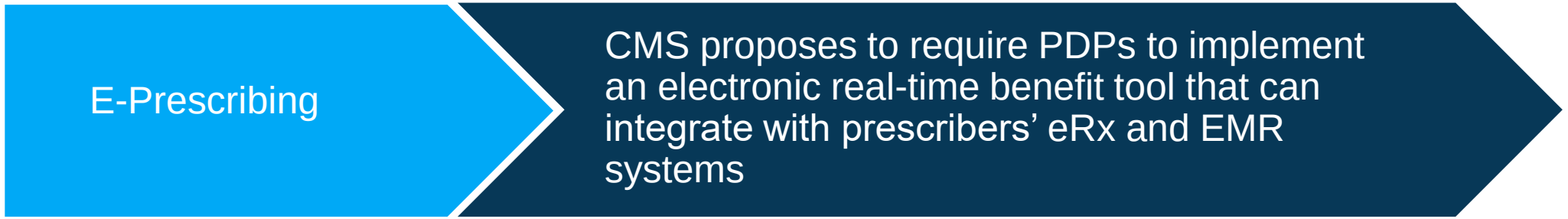
*This would include all variations in strength, dosage, and routes of administration

CMS Proposes Three Policy Changes That Would Impact Protected Class Drugs

CPI-U	Whether an alternative pricing threshold to CPI-U should be considered
WAC	Whether a substitute to WAC as a pricing standard should be used
Exclusion	Whether a Part D sponsor should be able to exclude: • A protected class drug from any future contract year • All drugs in the protected classes of a given manufacturer
Application	If the proposed exception should apply to only single-source drug and biological products or be expanded to a broader mix of drugs
Monitoring	Whether Part D sponsors or CMS should monitor changes in WAC and CPI-U
Baseline WAC	Whether the baseline WAC date of September 1, 2018 should be used for drugs that were first marketed in the US on or before September 1, 2018

CMS: Centers for Medicare & Medicaid Services; CPI-U: Consumer Price Index – Urban; WAC: Wholesale Acquisition Cost

A Real-Time Benefit Tool Would Provide Information on a Drug's Price and Therapeutic Alternatives



With this proposal, CMS hopes to increase drug price and coverage transparency to prescribers and beneficiaries at the site of care, rather than at the point of sale

CMS: Centers for Medicare & Medicaid Services; PDP: Prescription Drug Plan; RTBT: Real-Time Benefit Tool; eRx: E-Prescribing; EMR: Electronic Medical Record

CMS Proposes to Codify Use of Step Therapy in Medicare Advantage, As Described in Guidance Earlier in 2018

Starting in 2019, CMS allows MA plans to use step therapy for all new prescriptions for part b-covered drugs

MA-PD Cross Management

- MA-PDs will have the ability to cross-manage between Part D and Part B drugs
- The majority of MA enrollees (89%) are enrolled in MA-PDs that will have this capability

Care Coordination Requirements

- CMS stipulates new requirements should be combined with drug management care coordination services
- Programs should include, at a minimum: interactive medication review and medication reconciliation, educational materials about therapeutic options, and medication adherence strategies

August 7 guidance being codified in rule allows MA plans to implement step therapy to require: (1) a Part D drug before a Part B drug; (2) a Part B drug before a Part D drug; or (3) a Part B drug before a Part B drug

MA-PD: Medicare Advantage Prescription Drug Plan; MA: Medicare Advantage; CMS: Centers for Medicare & Medicaid Services

Connect with Us

@avalerehealth

Avalere Health

avalere.com

Avalere®

Part D Proposed Rule – Overview of 6PC Changes

	Currently allowed?	Allowed under proposed rule?
Prior authorization or step therapy for any use of HIV/AIDS meds (new starts or stable patients)	X	✓
Prior authorization or step therapy for new starts of other 6PC meds	✓	✓
Prior authorization or step therapy for 6PC drugs for currently stable patients	X	✓
Excluding new formulations from 6PC even if previous formulation taken off the market	X	✓
Excluding drugs from 6PC for prospective price increases above CPI-U	X	✓