

## Medicare Part D for Patients with Prostate Cancer

# Did you know?

You can help patients with prostate cancer overcome barriers to access their medicine!

### There is no one-size-fits-all treatment for patients with prostate cancer<sup>1</sup>

- Patients with prostate cancer may respond differently to various drugs
- Treatment decisions belong with patients and their doctors

### Medicare Part D plans manage oral oncology drugs through a formulary (drug list)<sup>2\*</sup>

- A drug will be covered under Part D if the prescription is filled by a retail pharmacy or a dispensing pharmacy at a doctor's office
- Part D formularies must meet the following requirements<sup>3†</sup>:
  - At least two chemically distinct drugs in each class or category<sup>3‡</sup>
  - Multiple strengths and dosage forms for each covered drug<sup>3</sup>
  - All or substantially all drugs in the six protected classes<sup>4§</sup>



Part D plans may restrict access to certain drugs on formulary. This may cause barriers for patients to obtain the drugs prescribed by their doctor.<sup>5,6||</sup>

\* Centers for Medicare & Medicare Services (CMS) requirements

† Medicare drug plans generally do not pay for over-the-counter drugs. Most Medicare drug plans exclude certain drug categories (eg, weight loss, sleep aids, etc), but some plans may offer them as additional benefits.

‡ Unless only one drug is available or if only two drugs are available, and one is clinically superior to the other

§ Medicare's Part D "six protected classes" policy includes oncology drugs. The six protected drug classes include: antineoplastics, anticonvulsants, antidepressants, antipsychotics, antiretrovirals, and immunosuppressants.




|| Subject to CMS approval. CMS established exceptions that allow plans to limit access to Part D protected class; plans can implement prior authorization (PA) and step therapy (ST) for new starts; however, this exception does NOT apply to antiretrovirals - Part D plans may not impose PA or ST requirements for antiretrovirals.

Medicare Part D plans restrict access to certain drugs using Utilization Management (UM) tools, which may cause variations in insurance coverage for prostate cancer therapies.<sup>5,7</sup>



## Utilization Management and Accessing Drugs

### Most Common Part D Utilization Management Tools

 UM Tools	 Purpose	 Potential Patient Impact
<b>Prior Authorization (PA) and Step Therapy (ST) for newly prescribed drugs.<sup>2*</sup></b>	<ul style="list-style-type: none"><li>• To confirm drug is in the protected class category<sup>†</sup></li><li>• To confirm drug is clinically appropriate</li><li>• To confirm drug meets the Part D requirements<sup>‡</sup></li><li>• To encourage use of lower-cost drug</li></ul>	May delay initiation or continuation of necessary treatment <sup>2,7</sup>
<b>Tier Placement<sup>3</sup></b>	To encourage use of lower-cost drugs by ranking drugs into groups (tiers). Specialty drugs are placed on high tiers.	Patients may have higher cost sharing. <sup>5</sup>
<b>Formulary Exclusions<sup>2,5</sup></b>	To control costs, plan may not cover all drugs if multiple clinically equivalent drugs are available within the same class.	Nonpreferred drugs deemed medically necessary must be obtained through the exceptions process.



**Despite the use of UM tools, patients may still gain access to their prescribed drugs.**

All Part D plans have an exceptions process that doctors can use to request coverage for drugs considered medically necessary for their patients.<sup>8</sup>

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‡ Centers for Medicare & Medicare Services (CMS) requirements

Doctors can request coverage for drugs they believe are medically necessary through an exceptions process.<sup>8</sup>



## Who starts the exceptions process?

- The doctor must submit supporting documentation (eg, via tiering exception<sup>\*</sup> or formulary exception<sup>†</sup>) to the Part D plan that the prescribed drug is medically necessary to treat the patient's condition.<sup>8</sup>

## When will the insurance plan notify the doctor of exception approval or denial?

- Plan must notify the patient and the doctor of its decision no later than 72 hours after receiving the prescriber's request and within 24 hours for expedited cases<sup>9</sup>
- If the exception request is denied, the patient (or the doctor acting on the patient's behalf) has the right to appeal<sup>‡</sup> for Part D plan reconsideration<sup>9</sup> per the Medicare Part D Appeals Process



The doctor must submit supporting documentation to the Part D plan that the drug is medically necessary to treat the patient's condition.<sup>8</sup>

<sup>\*</sup> Tiering exception: the doctor's supporting statement must indicate that the preferred drug(s) would not be as effective as the requested drug for treating the patient's condition, the preferred drug(s) would have adverse effects for the patient, or both.

<sup>†</sup> Formulary exception: the doctor's supporting statement must indicate that the non-formulary drug is necessary for treating a patient's condition because: (1) All covered Part D drugs on any tier would not be as effective or would have adverse effects. (2) The number of doses under a dose restriction has been, or is likely to be, less effective. (3) The alternative(s) listed on the formulary or required to be used in accordance with step therapy has (have) been, or is (are) likely to be, less effective or have adverse effects.

<sup>‡</sup> Appeals process is separate from the exceptions process.



## Additional Resources

### PART D EXCEPTIONS PROCESS:

<https://go.cms.gov/34pM75b>

### PART D APPEALS PROCESS:

<https://go.cms.gov/2xjBUej>

### JANSSEN CAREPATH:

<https://bit.ly/3e9r5vT>

### KNOW YOUR STATE INTERACTIVE TOOL:

<https://bit.ly/39VyaNv>

### SUPPORTING APPROPRIATE PAYER COVERAGE DECISIONS:

<https://bit.ly/3c7xIT5>

### ADVOCACY CONNECTOR:

<https://bit.ly/2Vj8m8D>

### ZERO360 HOTLINE:

<https://bit.ly/3c6lt2E>

## Glossary of Select Terms

**FORMULARY:** A list of prescription drugs covered by a Part D plan. Also called a drug list<sup>2</sup>

**FORMULARY EXCLUSION LIST:** A list of prescription drugs that are not included/not covered on the Part D plan formulary<sup>5</sup>

**PREFERRED DRUG:** Prescription drugs that the Part D plan formulary prefers to be prescribed first<sup>10</sup>

**PRESCRIPTION DRUG COVERAGE:** Health insurance or plan (eg, Medicare Part D) that helps pay for prescription drugs and medications<sup>11</sup>

**PRIOR AUTHORIZATION:** Requires a patient to meet certain criteria and receive advance permission before the plan will cover a prescription drug<sup>10</sup>

**STEP THERAPY:** Requires patients to try a lower-cost medication for a period of time before gaining coverage for a higher cost medication<sup>10</sup>

**TIER PLACEMENT:** To lower costs, many prescription drug plans place drugs into tiers on their formularies. Tier organization varies by plan. Generally, a patient will pay less out-of-pocket for a drug in a lower tier than a drug in a higher tier.<sup>12</sup>

### Sample Tier Organization

Tier	Description
1	Lowest copayment: most generic prescription drugs
2	Medium copayment: preferred, brand-name prescription drugs
3	Higher copayment: nonpreferred, brand-name prescription drugs
Specialty	Highest copayment: very high-cost prescription drugs

**UTILIZATION MANAGEMENT:** Controls (or “restrictions”, “usage management”) that Part D plans can place on prescription drugs. Examples include prior authorization, step therapy, tier placement, and formulary exclusions.<sup>13</sup>

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