

**STATE MEDICAID ALTERNATIVE REIMBURSEMENT AND PURCHASING TEST FOR HIGH-COST DRUGS (SMART-D)**

# Medicaid High-Cost Drug Carve-Out Policy Considerations

Therapeutic innovations have led to the availability of effective, but expensive, novel drug therapies for conditions that have had limited treatment options. While these innovative therapies may offer life-changing clinical outcomes for patients, there are also significant financial implications for payers and hospitals. Special financial considerations apply when Medicaid is the payer, due to the unique financing of the program. To ensure access to new treatment options, states are turning to specialized payment methodologies that uniquely apply to high-cost drugs, frequently referred to as high-cost drug carve-out policies. This brief explores the key policy and operational considerations for implementing high-cost drug carve-out policies for inpatient and outpatient hospitals, and for managed care programs supporting Medicaid members.

Manufacturers can price new treatments in various ways, but ultimately, prices are set at a level that manufacturers believe the market will bear. The combination of patents granting effective monopolies, insurance pooling individual health care costs and redistributing them across broader populations, and access mandates for the Medicaid program effectively create a scenario where the market will bear exceptionally high pricing. For example, Zolgensma, a well-known drug that treats spinal muscular atrophy, has a list price of \$2.19 million.<sup>1</sup> This and other extreme high-cost drug examples are shown in Table 1. While these drugs may have a real positive impact on patient lives, the financial impact can be equally profound, albeit less positive for the entities purchasing these drugs.

**TABLE 1**  
**High-Cost Drug Examples**

| Generic Name                  | Brand Name | Condition Treated   | Average Annual Cost, <sup>1,2</sup> \$ |
|-------------------------------|------------|---|--|
| Onasemnogene abeparvovec-xioi | Zolgensma  | Spinal muscular atrophy   | 2,188,000                              |
| Metreleptin                   | Myalept    | Complications of leptin deficiency in patients with generalized lipodystrophy                                 | 1,260,000                              |
| Lonafarnib                    | Zokinvy    | Used to lower the risk of death in Hutchinson-Gilford Progeria Syndrome                                       | 1,070,000                              |
| Naxitamab-gqgk                | Danyelza   | Relapsed or refractory high-risk neuroblastoma  | 1,010,000                              |
| Tebentafusp-tebn              | Kimmtrak   | Relapsed or refractory classical Hodgkin lymphoma   | 975,520                                |
| Pralatrexate                  | Folotylin  | Peripheral T-cell lymphoma  | 842,585                                |
| Interferon gamma 1-b          | Actimmune  | Used to reduce the frequency and severity of serious infections associated with chronic granulomatous disease | 819,000                                |
| Eculizumab                    | Soliris    | Paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome                                    | 764,000                                |
| Cerliponase alfa              | Brineura   | Batten disease  | 755,898                                |
| Blinatumomab                  | Blincyto   | Acute lymphoblastic leukemia  | 754,720                                |
| Glycerol phenylbutyrate       | Ravicti    | Urea cycle disorders  | 695,970                                |

Source: Bosworth et al., 2023<sup>1</sup> and RxBenefits.<sup>2</sup>

The financial burden of high-cost drugs provided to Medicaid members falls to the Medicaid program (shared state and federal financial accountability), contracted Medicaid managed care entities, and hospitals at which Medicaid members receive care; the distribution of this financial accountability depends on how a state structures Medicaid hospital reimbursement and managed care financial policy. High-cost drug carve-out policies are designed to shift some of or all the financial accountability from hospitals and managed care entities to the Medicaid program. This is typically done with the intention of preserving patient access to innovative treatments or in response to hospital or managed care entity feedback. Because Medicaid has regulatory obligations for ensuring access to covered benefits for its members, carve-out policies are becoming more and more necessary.

With a growing pipeline of anticipated high-cost drugs entering the market in coming years, this financial and patient access challenge will only continue to grow.

Policy and implementation considerations for a high-cost drug carve-out will vary depending on the specific drug delivery setting (outpatient or inpatient); managed care plans have a different set of considerations altogether. The following sections explore relevant considerations for inpatient and outpatient hospitals, and separately for managed care plans.

## HIGH-COST DRUG CARVE-OUT FOR HOSPITALS

Hospitals that dispense high-cost drugs to treat Medicaid members can face a significant financial burden due to the disparity between Medicaid reimbursement rates and the actual costs of acquiring and administering these medications. State Medicaid programs often cover the costs of expensive specialty medications under their hospital benefits when the medication is administered as part of an inpatient hospital stay or an outpatient visit. In such instances, Medicaid may not directly reimburse for the drug. Instead, Medicaid programs frequently pay for the therapies as part of a bundled payment that is meant to cover costs of medical care received during the inpatient stay or outpatient visit. Common examples of these methodologies include per diems or the All Patient Refined Diagnosis Related Groups (APR-DRG) methodology for inpatient hospital service, and the Ambulatory Patient Group (APG) or Enhanced Ambulatory Patient Group (EAPG) for outpatient hospital services.

To illustrate the fiscal impact of bundled payment reimbursement methodologies that undercompensate for high-cost drugs, consider the following example. In fiscal year (FY) 2022, inpatient stays involving cost for chimeric antigen receptor (CAR) T-cell therapies treatment were assigned to Medicare Severity Diagnosis-Related Group (MS-DRG) 018, with a base reimbursement rate of \$246,955. In contrast, the average acquisition cost for CAR T-cell therapies range between \$373,000 to \$475,000 per infusion.<sup>3</sup> The fiscal impact to hospitals can be far more extreme than this example. While this type of treatment has a specific DRG, many other treatments do not. When drugs can cost over a million dollars, the reimbursement gap can be large.

While drug manufacturers do offer patient assistance programs and discounts in the form of rebates, options for reducing hospital acquisition costs are constrained by provisions of the antikickback statute found in §112B(b) of the Social Security Act.<sup>4</sup> On May 5, 2003, the Office of Inspector General of the Department of Health and Human Services issued guidance to drug manufacturers, identifying situations that may create the greatest risk of violating the antikickback statute.<sup>5</sup> Among these was the question, “[d]oes the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Drug Rebate Program Best Price calculation?” Drug manufacturers cannot generally offer financial incentives to hospitals or medical professionals to use a product that is purchased with federal funds.

Safety net hospitals can enroll in the 340B program, which allows access to discounted covered outpatient drugs, but unless the Medicaid reimbursement method covers the full costs of the treatment, including the drug, there could still be a significant cost gap between the 340B ceiling or subceiling price and the hospital inpatient or outpatient reimbursement. Consequently, without carve-out policies, hospitals may face severe financial losses when providing these treatments to their patients. If a hospital is in a position of losing millions of dollars each time they provide a service, patient access to the medication is very likely to suffer.

Outside of a capitated agreements with hospital systems, inpatient and outpatient hospital services almost always have different reimbursement methodologies. Because high-cost drug carve-out policies are implemented to explicitly address differences between the Medicaid reimbursement and the acquisition plus administration costs, these differences in methodology are important when evaluating carve-out policy options. We first discuss general considerations that apply in both settings, and then identify considerations that uniquely apply to each. Policy considerations are generally organized into the following categories:

- Should high-cost drugs be carved out of existing reimbursement methodologies for hospitals?
- Which high-cost drugs should be carved out?
- What is the reimbursement method for the carved-out drugs?
- What are important implementation and operational considerations?

### Should High-Cost Drugs Be Carved Out of Existing Reimbursement Methodologies?

The first question to consider is whether any high-cost drugs should be carved out from the reimbursement methodologies for hospitals. As previously described, the primary question is about patient access to medically necessary treatments. Medicaid has 2 primary regulatory access mandates. The first is the general requirement that states must “assure that payments are consistent with efficiency, economy, and quality of care, and are sufficient to enlist enough providers so that care and service areas are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.”<sup>6</sup> The second requirement applies to children under the age of 21; the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) mandate broadly requires that children and adolescents receive all medically necessary health care, services, and treatment.<sup>7</sup> If access to high-cost drugs is limited by the standard hospital reimbursement methodologies, there is a reasonable regulatory rationale that a carve-out policy should be adopted, particularly if access to the drug is being limited to children and adolescents. Separately, hospital fiscal solvency and or other political factors could be compelling rationales for a carve-out policy.

## Which High-Cost Drugs Should Be Carved Out?

State Medicaid programs are adopting different strategies for identifying drugs to be included in a high-cost drug carve-out. The spectrum of options ranges from ongoing case-by-case evaluation, to prospectively defining the characteristics of a drug that would trigger inclusion in the high-cost drug carve-out policy. For example, Colorado implemented a high-cost drug carve-out policy that limits carve-outs to drugs included on the “Outpatient Hospital Specialty Drug” list. Drugs included on Colorado’s carve-out list at the time of writing are shown in Table 2. Similarly, Vermont leverages a “High-investment Carve-Out Drugs List” to indicate to which drugs their inpatient carve-out policies apply.<sup>8</sup> Massachusetts also uses a carve-out drug list rather than setting a policy at a given price point.<sup>9</sup>

**TABLE 2**  
**Colorado Outpatient Hospital Specialty Drugs<sup>10</sup>**

| Generic Name                  | Brand Name | Manufacturer            | Condition Treated                                    |
|-------------------------------|------------|-------------------------|--|
| Lisocabtagene maraleucel      | Breyanzi   | Bristol Myers Squibb    | Diffuse large B-cell lymphoma                        |
| Cerliponase alfa              | Brineura   | BioMarin Pharmaceutical | Late infantile neuronal ceroid lipofuscinosis type 2 |
| Ciltacabtagene autoleucel     | Carvykti   | Blueprint Medicines     | Gastrointestinal stromal tumor                       |
| Naxitamab-gqgk                | Danyelza   | Y-mAbs Therapeutics     | High-risk neuroblastoma                              |
| Tisagenlecleucel              | Kymriah    | Novartis                | Diffuse large B-cell lymphoma                        |
| Nusinersen                    | Spinraza   | Biogen                  | Spinal muscular atrophy                              |
| Brexucabtagene autoleucel     | Tecartus   | Gilead Sciences         | Mantle cell lymphoma                                 |
| Ravulizumab-cwvz              | Ultomiris  | Alexion Pharmaceuticals | Paroxysmal nocturnal hemoglobinuria                  |
| Olipudase alfa                | Xenopozyme | Xenon Pharmaceuticals   | X-linked hypophosphatemia                            |
| Axicabtagene ciloleucel       | Yescarta   | Gilead Sciences         | Diffuse large B-cell lymphoma                        |
| Onasemnogene abeparvovec-xioi | Zolgensma  | Novartis                | Spinal muscular atrophy                              |

An alternative to actively managing a drug carve-out list would be to set specific price points above which a drug is carved out, or another consistent indicator such as the condition treated. The choice of strategy comes down to administrative simplicity versus maintaining the flexibility to actively manage the set of drugs to which the policy applies. Because dose frequency, disease prevalence, and cost per dose vary from drug to drug, the fiscal impact on hospitals can vary in ways that are difficult to capture with a catchall dollar-per-dose cutoff. This could result in frequent state plan amendments with a fixed price point policy; maintaining the flexibility to easily update the carve-out list as new treatments come onto the market could reduce administrative burden in the long term. Given these considerations, an actively managed high-cost drug carve-out list is likely preferable for most states considering a high-cost drug carve-out policy.

### What Factors Should Be Considered When Setting a Carve-Out Policy

Whether using a case-by-case review strategy or a defined set of parameters to identify drugs, there is no hard and fast rule for determining which specific drugs should be included in a carve-out policy; however, there are several key considerations to support a state's decision-making process including the following:

- Intersection with other policies
- Fiscal impact for hospitals, and resulting patient access to care considerations
- Fiscal impact for the state
- Stakeholder engagement

#### Intersection With Other Policies

A carve-out policy should retain sufficient flexibility to ensure the state Medicaid agency can include or exclude drugs based on whether a specific drug is affected by other policy initiatives. For example, states can opt to participate in the Cell and Gene Therapy Access Model, initiated by the Centers for Medicare & Medicaid Services (CMS).<sup>11</sup> This model focuses on increasing access to high-cost treatments, particularly cell and gene therapies. When a state participates in the model, they gain access to discounted pricing for the therapies via enhanced rebates, but in return must ensure specific coverage standards. These standards will likely require states to address significant reimbursement shortfalls to hospitals. To access the rebates, the drugs affected by the model may also need to be carved out from inpatient and outpatient reimbursement methodologies when they include bundled payment. While this model has initially focused on treatments for sickle cell disease, the suite of therapies included will expand over time. As this example illustrates, it can be beneficial for carve-out policies to be sufficiently flexible to accommodate shorter-term changes to the list of drugs to which the policy applies.

## **Fiscal Impact for Hospitals and Related Access-to-Care Considerations**

When devising a carve-out policy, assessing the financial implications for hospitals is crucial due to factors like patient access to treatments and the financial health of these facilities. Identifying areas where significant financial challenges arise without such a policy can guide its formation, especially in deciding which drugs to include or exclude. Essential factors in evaluating the financial impact of a carve-out for high-cost drugs include analyzing various high-cost drug scenarios, the procurement costs for these drugs, how they are reimbursed under current Medicaid payment schemes for medical facilities, and the timing issues regarding reimbursement following the high-cost drug purchase.

### ***Different High-Cost Drug Scenarios***

A fiscal impact analysis of a high-cost drug on hospitals must include more than just looking at the one-time cost of administering a drug. Some drugs have a lower list price but a larger population of eligible patients, or a more frequent administration schedule, the fiscal impact of which can be no less profound for hospitals. These 3 factors (price, population, and frequency of administration) produce a variety of fiscal impact scenarios that should be addressed through the high-cost drug policy.

### ***Hospital Acquisition Costs***

Hospital acquisition costs can vary by facility, but the primary driver of significant price differences at the hospital level is whether it is participating in the 340B Drug Pricing Program. The 340B program supports qualifying hospitals in accessing discounted outpatient drugs.<sup>12</sup> In concept, drugs purchased through this program are already rebated, and this discount results in a significantly lower acquisition cost.

### ***Reimbursement Under Existing Medicaid Hospital Payment Methods***

Given the purpose of a high-cost drug carve-out is to remediate inadequacies in existing payment methodologies, it is essential to understand precisely where these inadequacies exist. Evaluating reimbursement under existing methods can be a complicated task because hospitals may receive reimbursement for service through multiple revenue streams, or hospitals can have hospital-specific reimbursement rates.

As we noted, there are several different bundled reimbursement methodologies commonly used for inpatient and outpatient services: including per diem reimbursement, DRG-based methodologies, and APG-based methodologies. For each of these, services are not reimbursed on a per-service basis, but are instead reimbursed using a standardized payment for a group of services informed by either the length of stay or the conditions being treated. High-cost drugs may fit well clinically with other services in the reimbursable service bundle, but the financial costs of the drug treatments can wildly exceed the level of reimbursement provided for the service bundle.

States also adopt reimbursement methodologies based on provider costs, such as the cost-to-charge ratio reimbursement methodology (CCR), and engage in cost-settlement processes as part of the methodology. Under these systems, states reimburse hospitals by paying a percentage of the charges billed. The actual costs are then reconciled, often through a cost report audit process. This approach is particularly noteworthy in the context of high-cost drug carve-out policies. The cost settlement process might be adequate to cover the full expenses associated with high-cost drugs; however, this method introduces potential challenges related to cash flow insufficiencies, which are important to consider.

As states evaluate a high-cost drug policy, the reimbursement design considerations including unique hospital designations (i.e., safety net hospitals), supplemental payments, and cash flow timing should be considered.

### Unique Hospital Type Designations

Many state Medicaid programs account for distinct hospital categories in their cost gap analysis, affecting reimbursement strategies. Special designations such as teaching hospitals and critical access hospitals influence these approaches. When such facilities dispense high-cost drugs, it is crucial to specifically evaluate the effects of a carve-out policy on these providers.

### Supplemental Payments

When evaluating the gap between a hospital's acquisition cost and reimbursement, it is important to incorporate all forms of reimbursement. In 2022, all state Medicaid programs had some form of supplemental payments for hospitals, although there is significant variation in the magnitude of supplemental payments made.<sup>13</sup> Depending on how the supplemental payments are calculated, a high-cost drug carve-out could impact both the amount and distribution of hospital supplemental payments.

### Cash Flow Considerations

State Medicaid programs may also need to evaluate hospital cash flow when designing high-cost drug carve-out policies. Even in scenarios where hospitals may be fully compensated for the costs of acquiring the high-cost drugs (such as with a cost-to-charge ratio reimbursement methodology, which is reconciled to 100% of reasonable costs), if full compensation takes a while to come in (which is often true with cost-settlement processes), special treatment of high-cost drugs may still be warranted to support hospital financial solvency.

### Fiscal Impact for the State

Carve-out policies represent a transfer of financial accountability for high-cost drugs, from hospitals or managed care entities to state Medicaid fee-for-service programs. Officials in these programs will have to weigh the financial consequences of a carve-out policy against patient access, health outcomes,

hospital solvency, and other political concerns. However, there is a major potential advantage to implementing a drug carve-out policy, which is the availability of rebates for inpatient use.

The Medicaid Drug Rebate Program (MDRP) allows states to collect rebates on covered outpatient drug utilization.<sup>14</sup> The MDRP provides a broad definition of covered outpatient drugs, encompassing all prescription drugs, biologics (other than vaccines), and insulin. However, it is subject to a limiting definition that assesses whether the drug was directly or indirectly reimbursed. If indirectly reimbursed as part of a bundled hospital inpatient or outpatient payment, then a drug would not be considered an outpatient covered drug and not be eligible for rebate under the MDRP. In contrast, “[i]f a drug and its cost can be separately identified on a claim for payment, it can be considered subject to direct reimbursement.”<sup>15</sup> Carving high-cost drugs out of existing inpatient reimbursement methodologies and subjecting them to direct reimbursement enables states to claim rebates on high-cost drugs that would otherwise be inaccessible.

### **Stakeholder Engagement**

Given the many factors influencing high-cost drug carve-out policy, stakeholder engagement is critical. Absent sufficient stakeholder engagement, state Medicaid programs may not correctly identify all the relevant details, including financial impacts and access considerations needed to develop an appropriate policy. Medicaid officials should consider implementing a stakeholder engagement process to support development of high-cost drug carve-out policy.

### **What Is the Reimbursement Methodology for Carved-Out Drugs?**

Once a state Medicaid program has determined if and what drugs would be carved out from different reimbursement methodologies, they must determine which reimbursement methodology will be used for the carved-out drugs. State Medicaid agencies tend to opt for reimbursement methodologies that reimburse hospitals for the actual acquisition cost of the drug. Importantly, this includes ensuring drugs purchased through the 340B program are reimbursed at the discounted 340B price.

The carve-out policy should also clearly address the administration fee component of the hospital’s reimbursement. If carved out of a reimbursement methodology such as inpatient DRG or outpatient EAPG, the separate payment for other services rendered in the service bundle should be sufficient to cover the costs of administering the drug, which is how most states have operationalized the administration fee. This strategy is used by many of the states included as examples in this report. If paying a separate administration fee, state Medicaid agencies should avoid the reimbursement policy common for physician-administered drugs, which is to have a percentage added on to the price of the drug (e.g., average sale price plus 6%). High-cost drugs will scale this add-on to a potentially unsustainable level, given the underlying cost of the drug. Instead, states should consider employing a flat fee or a schedule of fees for administration. Once designed, the reimbursement methodology will need to be approved by CMS through a State Plan Amendment.

## What Are Important Implementation and Operational Considerations?

Once carve-out policies have been developed, the state Medicaid officials must determine how the policy is put into operation. The operational strategy will vary by state based on administrative capacity and existing infrastructure. For example, some of the Medicaid programs we reviewed implemented manual invoice-based processes. Others, such as Vermont Medicaid, have the hospital submit a separate claim through the claims processing system.<sup>8</sup> Sample operational and implementation questions to be addressed in state Medicaid high-cost drug policies are shown below, and categorized into billing and payment processes, impacts to existing reimbursement methodologies, and authority mechanisms.

### Billing and Payment Processes

- How does the state Medicaid agency ensure that hospitals accurately report net cost for the high-cost drug?
- What information needs to be captured, either on invoices or through the claims processing system, to ensure rebates can be claimed for use of the high-cost drug?
- What information needs to be captured through the billing process, and what processes need to be put in place to ensure rebates are not claimed for 340B utilization?
- How does the billing and payment process for carve-out drugs connect with the prior authorization process?
- How does the billing and payment process for carved-out drugs ensure that the transaction is recorded in the Medicaid Management Information System (MMIS), as required by CMS?
- How does the billing and payment process produce a properly coded transaction to ensure the correct federal match rate is claimed?

### Impacts to Existing Reimbursement Methodology

- Are any adjustments needed to the cost settlement or supplemental payment calculation processes?
- When the state is using a methodology that pays for groups of clinically related service bundles such as inpatient DRG or EAPG, are any adjustments to the underlying reimbursement methodology needed (e.g., adjustment to grouper weights)?

### Authority Mechanisms

A high-cost drug carve-out policy will require a State Plan Amendment to each impacted reimbursement methodology. Examples of approved State Plan Amendments supporting high-cost drug carve-out policies are included in [Appendix A](#). State Medicaid programs will likely need to update state-level rules and regulations as well.

## HIGH-COST DRUG CARVE-OUT FOR MANAGED CARE ORGANIZATIONS

Medicaid agencies are faced with the financial implications of high-cost drugs on multiple fronts. In addition to patient access and hospital financial solvency challenges, states can also face high-cost drug complications with their contracted managed care entities. Due to the difference in financial relationships between managed care entities and state agencies, compared with hospital and state agencies, a different set of considerations are relevant when considering a high-cost drug carve-out policy for managed care plans. Policy considerations are generally organized into the following categories:

- Should the state carve out high-cost drugs from managed care contracts?
- Which high-cost drugs should be carved out and how?
- What are additional implementation and operational considerations?

### Should the State Carve Out High-Cost Drugs From Managed Care Contracts?

As with high-cost drug carve-outs at the hospital level, answers to this question are highly reliant on state-specific context. Federal regulations require actuarially sound capitation rates, which are defined as “projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO [managed care organization], PIHP [prepaid inpatient health plan], or PAHP [prepaid ambulatory health plan] for the time period and the population covered under the terms of the contract.”<sup>16</sup> This could be interpreted to mean that if the cost and usage rates of high-cost drugs are known prospectively, the costs should be included in the managed care rates. Rates are typically set for a 12-month period and must be submitted 90 days prior to the effective rating period. Factors such as uncertainty about the timing of market entry, the population that will use the drug, as well as the drug’s acquisition price at market entry, make accurate prospective adjustment of managed care rates to account for new (or even existing) high-cost drugs in advance of when the usage may occur exceptionally difficult. Additionally, there is financial risk for the state, too, as the state could spend more than intended if high-cost drug experience is included in future rates and the usage does not manifest as expected. Given these dynamics, several states have opted for some form of high-cost drug carve-out. The Kaiser Family Foundation reports that 19 of 37 responding states had drug carve-out policies for 1 or more classes of drugs for their managed care carve-out.<sup>17</sup> Specific examples of high-cost drug carve-outs in managed care can be found in [Appendix B](#).

Separately, it is worth noting that some states carve out the pharmacy benefit in entirety. However, because high-cost drugs can be provided under the inpatient and outpatient hospital benefits (or even under other service categories such as Indian Health Services), states with pharmacy benefit carve-outs for managed care may still need to address high-cost drug carve-outs. This is especially important to consider for practitioner-administered drugs paid under the medical benefit for their managed care

contracts. The following questions are intended to support states in thinking through the complex decision of whether to carve high-cost drugs out of managed care:

- Does state fiscal policy support the risk of overpayment or underpayment from forecast errors in the rate-setting process related to high-cost drugs?
  - Are managed care plans asking for a carve-out?
  - Is a carve-out permissible under the state's statute?
  - What are the existing financial risk-sharing and mitigation strategies (e.g., risk corridors, risk pools, outlier payments) in place for managed care?
- » How would a high-cost drug interact with these mechanisms?
- » Is a carve-out necessary, given current risk mitigation tools in play?
- Can the rate-setting process accurately capture the financial risk associated with high-cost drugs?
  - Is your state willing to submit off-cycle rate updates in the event of extreme market shocks from new high-cost drugs entering the market?
  - What is the historical financial performance of the state's contracted MCOs?
  - Does each MCO plan have enough covered lives or large enough risk pool to absorb high-cost drug outliers?
  - Could the carve-out be for a limited duration until there is an accurate assessment of costs and usage that could be included in future managed care rates?

### Which High-Cost Drugs Should Be Carved Out and How?

Managed care plans are designed to take on financial risk for service use. How much risk they take on, and whether that should include the risk of emerging technologies, and not just risk associated with general service use, is a question that each state must answer individually. Factors such as the state's overall risk tolerance and relationship with MCOs as well as answers to questions like those noted above are important to consider. State Medicaid agencies should coordinate with their managed care plans when developing high-cost drug carve-out policies.

Structurally, there are different options for high-cost drug carve-out policies. States such as Colorado have implemented a managed care high-cost drug carve-out that offers additional payment to the MCO for any drugs on a predefined list that exceed \$100,000 per treated client.<sup>18</sup> New Hampshire fully carved out any prescribed drugs for the treatment of hepatitis C and hemophilia, as well as the high-cost drugs carglumic acid (Carbaglu) to treat high blood-ammonia levels, and glycerol phenylbutyrate (Ravicti) for certain urea cycle disorders; they are paid through fee-for-service.<sup>19</sup> As with the amount of financial risk, the structure of the risk-mitigation strategy should be the result of collaboration and negotiation between the state and contracted plans.

## What Are Additional Implementation and Operational Considerations?

Many of the implementation and operational considerations from the [hospital inpatient and outpatient section](#) above also apply to managed care. The key difference is that each process should clearly define the role of the managed care entity. Additional considerations specific to managed care include:

- How would a carve-out interact with the rate-setting process, including accounting for reduction in costs for services that are no longer needed after receiving the treatment?
- With multiple payers involved, how does the state ensure consistent prior authorization and reimbursement policies for both patients and hospitals?

## SUMMARY

High-cost drugs can represent life-changing therapies for many conditions for which there previously were limited treatment options. These drugs also bring tremendous financial challenges for hospitals and payers, including state Medicaid agencies. To protect access to care for patients, and financial solvency for hospitals and contractors, state agencies are faced with developing high-cost drug carve-out policies. In this brief, we provided an overview of the considerations for developing high-cost drug carve-out policies, and provided examples of strategies already implemented by states around the country.

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## APPENDIX A

### SELECT STATE REFERENCES FOR HIGH-COST DRUG CARVE-OUTS ACROSS DIFFERENT SERVICE CATEGORIES

#### Colorado

##### Outpatient Hospital

*Modifies the reimbursement methodology for drugs administered in the outpatient hospital setting that are paid outside of the EAPG methodology.*

- [Colorado State Plan Amendment CO 23-043, March 27, 2024](#)

##### Inpatient Hospital

*Modifies the reimbursement methodology for drugs administered in the inpatient hospital setting that are paid outside of the APR-DRG reimbursement methodology.*

- [Colorado State Plan Amendment CO 23-042, March 27, 2024](#)

#### New York

##### Outpatient Hospital

*“Never Pay Procedures,” carve-outs from Ambulatory Patient Groups outpatient hospital reimbursement methodology.*

- [Ambulatory Patient Groups \(APG\) Reimbursement Methodology \(ny.gov\)](#)

#### Vermont

##### Inpatient Hospital

*Establishes reimbursement carve-out through Vermont’s waiver program “Global Commitment to Health.”*

- [State of Vermont Global Commitment Register: Reimbursement for High-Investment Carve-Out Drugs, January 24, 2023](#)
- [Department of Vermont Health Access High-Investment Carve-Out Drugs List, October 1, 2023](#)

## APPENDIX B

### SELECT STATE REFERENCES FOR HIGH-COST DRUG CARVE-OUTS IN MANAGED CARE

#### Indiana

##### Managed Care

*Bulletin describing managed care carve-out for certain drugs.*

- [Indiana Health Coverage Program Bulletin BT202110, February 16, 2021](#)

#### Michigan

##### Managed Care

*Identifies list of injectable drugs and biologicals that are carved out of managed care and paid on a fee-for-service basis.*

- [MDHHS Medicaid Health Plan Injectable Drugs and Biological Carve-out, April 2024](#)

#### New Hampshire

##### Managed Care

*Establishes fee-for-service reimbursement (managed care carve-out) for drugs that treat hepatitis C and hemophilia, and for carglumic acid (Carbaglu) and glycerol phenylbutyrate (Ravicti).*

- [New Hampshire SPA 16-0016, November 1, 2016](#)

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