



TEXAS  
Health and Human  
Services

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# **Texas Vendor Drug Program**

## **Drug Addition Process**

January 2021

[txvendordrug.com/about/manual/pharmacy](http://txvendordrug.com/about/manual/pharmacy)

# Table of Contents

<b>Table of Contents</b> .....	<b>2</b>
<b>1 About the Process</b> .....	<b>3</b>
<b>2 Formulary Drug Addition</b> .....	<b>3</b>
2.1 TDCI Eligibility .....	3
2.2 Population Impact .....	4
2.3 Cost Per Prescription .....	5
2.4 Fiscal Impact .....	5
2.5 Fiscal Analysis .....	5
2.6 Review of Fiscal Analysis .....	6
<b>3 Clinician-Administered Drug Addition</b> .....	<b>6</b>
3.1 Determining Medical Benefit Eligibility .....	6
3.2 Determining Drug Price and Rebate Amount .....	7
3.3 Estimating Utilization .....	7
3.4 Estimating First-Year Fiscal Impact .....	7
3.5 Drafting LBB Notice or Approval .....	8
<b>4 Contacts</b> .....	<b>8</b>

# 1 About the Process

Drug manufacturers complete the Texas Drug Code Index (TDCI) Certification of Information (COI) to request the addition of the drug on the Medicaid and CHIP formularies. VDP uses the COI when a drug is new to the market or when an existing drug on the TDCI has a new formulation or labeler changes. We will also review the COI to ensure drugs meet federal and state requirements.

The Legislative Budget Board (LBB) and Office of the Governor must approve any drug estimated to meet or exceed \$500,000 in annual general revenue in fee-for-service per state fiscal year or result in a managed care capitation rate adjustment.

The exception to this is orphan drugs, per the 2020-21 General Appropriations Act, House Bill (H.B.) 1, 86th Legislature, Regular Session, 2019 (Article II, Special Provisions Relating to All Health and Human Services Agencies, Section 14(c)). There is no LBB or Governor's approval requirement for the addition of orphan drugs to the TDCI. Notification of a new or increased rate for an orphan drug must be submitted to the LBB and Governor within 60 days following expenditures for the purpose.

VDP will complete the initial analysis of new drugs no later than 30 days after receiving the completed COI. Our timely review ensures HHS Forecasting and HHS Executive Leadership have at least 60 days to complete the fiscal impacts and obtain LBB approval. We will alert HHS Forecasting as quickly as possible (approximately on day 15 of the process) about drugs potentially requiring the need for LBB approval. This will allow HHS Forecasting staff more time to complete a fiscal impact.

VDP identifies orphan drugs qualifying for coverage and adds them to the TDCI. Notification regarding a new or increased rate for orphan drugs is submitted to the LBB and Governor within 60 days.

Questions or comments regarding this process should be submitted to [vdp\\_formulary@hpsc.state.tx.us](mailto:vdp_formulary@hpsc.state.tx.us).

## 2 Formulary Drug Addition

### 2.1 TDCI Eligibility

#### 2.1.1 Day one

The formulary addition process begins when the drug manufacturer submits the completed COI requesting the inclusion of their drug to the TDCI. VDP pharmacists

start by reviewing the [Centers for Medicare & Medicaid Services \(CMS\) rebate file](#) to determine if the drug has a rebate agreement. If the National Drug Code (NDC) is not on the CMS rebate file within six months, the process stops.

Next, staff will identify whether the U.S. Food and Drug Administration (FDA) includes the drug on the Orphan Drug Product designation database ([accessdata.fda.gov/scripts/opdlisting/oopd/](https://accessdata.fda.gov/scripts/opdlisting/oopd/)).

VDP pharmacists will determine if the drug is eligible as a clinician-administered drug (CAD) via the medical benefit.

- If the drug is not covered as a medical benefit, then staff proceed to Section 2.2 below.
- If the drug is covered as a medical benefit, staff use clinical expertise to determine if the CAD is appropriate for distribution through a pharmacy:
  - ▶ If the drug is not appropriate for distribution through a pharmacy, then it becomes a medical benefit and is not added to the TDCI (refer to Section 3 below).
  - ▶ If the drug is appropriate for distribution through a pharmacy, then staff proceed to Section 2.2 below.

## 2.2 Population Impact

VDP pharmacists will estimate the potential use of the drug by people enrolled in Medicaid by reviewing the following:

- NDC package inserts and indications
- Compendia and epidemiology clinical studies
- Texas Medicaid claim and encounter utilization (in situations when a manufacturer replaces one NDC with another)
- CMS website (<https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/>) to identify if other states have reported drug utilization data for the NDC). The data includes state, drug name, NDC, number of prescriptions, and dollars reimbursed if available.
- Other sources, such as specialty pharmacies, manufacturers, and various foundations.

The pharmacist will determine if the drug requires clinical prior authorization and, if needed, develops the criteria. Using clinical judgment and the information gathered above, the pharmacist will then estimate the number of people enrolled in fee-for-service and managed care who meet the coverage requirements.

## **2.3 Cost Per Prescription**

The VDP pharmacist estimates the cost per prescription by doing the following:

1. Querying First Data Bank to obtain the National Average Drug Acquisition Cost or the Wholesale Acquisition Cost price. If those price points are not available, staff use the Average Wholesaler Pricing and the Net Cost to Wholesaler price from the COI. The pharmacist does not include the dispensing fee in the cost estimate.
2. Reviewing the drug package insert and determining any requirements with the potential to limit the quantity or duration of drug therapy
3. Calculating the maximum quantity allowed and the estimated cost per prescription.

## **2.4 Fiscal Impact**

### **2.4.1 Ends Day 30**

The VDP pharmacist estimates the fiscal impact by doing the following:

1. Calculating the estimated number of prescriptions by multiplying the estimated number of people who may use the drug by the average number of prescriptions per year.
2. Calculating the estimated cost by multiplying the estimated number of prescriptions by the cost per prescription.
3. Calculating the federal financial participation and general revenue (GR) of the estimated costs determined above.
4. For orphan drugs and any drug for which the estimated GR FFS cost meets or exceeds \$500,000 per state fiscal year or results in a managed care capitation rate adjustment, engages Forecasting staff for further evaluation:
  - a. If there is potential for a drug to equal or exceed \$500,000 GR FFS costs per state fiscal year or result in a managed care capitation rate adjustment, then the drug is referred to Forecasting for further analysis.
  - b. If VDP identifies the drug as an orphan, then the drug is added to the TDCI. VDP will coordinate with Forecasting to prepare and submit the required orphan drug notification within 60 days as required under Special Provision 17. As noted above, LBB is not required to approve orphan drugs.

## **2.5 Fiscal Analysis**

### **2.5.1 Begins Day 31**

HHS Forecasting staff project the fiscal impact to obtain rate approval for the drug's potential addition by doing the following:

1. Obtaining data to perform their analysis. This is an interactive process with VDP staff to obtain drug pricing, rebate revenue data, potential drug cost offsets, and utilization assumptions. Other data collection varies by drug.
2. Completing gross drug cost projection analysis based on the number of utilizers, cost per prescription, and ingredient cost.
3. Calculating net drug cost by incorporating rebate revenue estimates for federal and supplemental (if applicable) rebates.
4. Calculating overall net cost impact after consideration of any potential cost offsets resulting from the drug's utilization.

## **2.6 Review of Fiscal Analysis**

### **2.6.1 Ends Day 90, As Needed**

The fiscal analysis is reviewed internally by VDP and HHS Actuarial Analysis and prepared for submission to external parties.

1. Actuarial Analysis reviews to determine if the expected cost of the drug requires an adjustment to managed care rates.
2. Actuarial analysis makes a recommendation regarding risk status.
3. Based on a drug's estimated fiscal impact, Provider Finance Department (PFD) determines what type of notice to or approval from the LBB is required. If approval is needed, VDP and the Financial Services Division coordinate to obtain the necessary approval.

## **3 Clinician-Administered Drug Addition**

### **3.1 Determining Medical Benefit Eligibility**

#### **3.1.1 Begins Day 1**

Clinician-administered drugs (CAD) or biologicals, also known as physician-administered drugs, are injectable medications given in an office or outpatient clinic setting when oral medications are not appropriate. CADs may be reimbursable as a medical benefit through Texas Medicaid. VDP reviews newly-released Healthcare Common Procedure Coding System (HCPCS) codes for CADs and biologicals. If VDP pharmacists determine the CAD is appropriate for Medicaid, then the HCPCS codes are presented at a rate hearing as part of the process to become a benefit.

A COI application is not necessary in order for staff to initiate review of the drug. HHSC's review of any new CAD does not guarantee the new CAD will become a benefit. Texas Medicaid follows these steps to approve CADs after FDA approves the drug and assigns the NDC:

The drug manufacturer signs a rebate agreement with CMS and once the drug is reflected on the CMS rebate file, Texas Medicaid begins a clinical and fiscal review for providing the drug benefit.

4. The drug manufacturer submits an application to CMS for the assignment of an HCPCS code. Once assigned, Texas Medicaid receives the newly-created HCPCS code on the quarterly CMS file.
5. VDP works with HHSC Rate Analysis to determine the fiscal impact and assign a rate to the drug through the interim process.

### **3.2 Determining Drug Price and Rebate Amount**

VDP pharmacists research the proposed reimbursement and rebates rates and provide the data to PFD to develop the drug's fiscal estimate. The pharmacist utilizes drug reference and pricing compendia to suggest reimbursement rates, unit rebate amounts, and related treatment costs.

### **3.3 Estimating Utilization**

VDP pharmacists identify utilization data to develop the estimate. When a more complex analysis is needed, the pharmacist submits a Benefit Management Review (BMR) Request to the HHS Center for Analytics and Decision Support (CADS). CADS research specialists estimate the number of people who may potentially use the drug by doing the following:

1. Using claims and encounters history to determine possible population.
2. Estimating population on the VDP-provided diagnosis codes, comparable procedure codes, and NDCs or related studies.
3. Referring to other sources as needed to gather additional information to provide a population estimate.

### **3.4 Estimating First-Year Fiscal Impact**

#### **3.4.1 Ends Day 30**

PFD staff will estimate the drug's first-year fiscal impact. The PFD analyst:

1. Determines the drug's pricing methodology per Texas Administrative Code (TAC) rule Section 355.8085 (e).
2. Determines the drug's estimated cost in the first year:
  - a. For drugs utilized by new client populations, then the cost estimates are determined using drug dosing and administration guidelines.
  - b. For drugs shifting from a currently covered drug, then the cost estimates are based on the currently-covered drug's utilization.

3. Calculates the Federal Financial Participation and estimated General Revenue (GR) cost by multiplying the estimated first-year cost by the Federal Medical Assistance Percentages (FMAP).

### 3.5 Drafting LBB Notice or Approval

#### 3.5.1 Ends Day 90, as Needed

Based on the amount of a drug's estimated fiscal impact:

1. PFD staff determine if the drug's coverage requires a notification or approval letter to LBB.
2. VDP drafts the notification or approval letter using fiscal impact estimates determined by PFD.
3. Actuarial Analysis staff review the drug's risk status and whether the drug will impact the managed care capitation rate. Staff will include this information as part of the notification or approval letter.
4. PFD schedules the letter for review by HHSC Executive Leadership before sending it to LBB.

## 4 Contacts

For further information or inquiries, contact the specific area at the email below:

VDP DUR/Formulary	<a href="mailto:VDP-Formulary@hhsc.state.tx.us">VDP-Formulary@hhsc.state.tx.us</a>
Provider Finance Department, Acute Care Services	<a href="mailto:RADAcuteCare@hhsc.state.tx.us">RADAcuteCare@hhsc.state.tx.us</a>
VDP Clinical Pharmacy and CAD Operations	<a href="mailto:vdp-cad@hhsc.state.tx.us">vdp-cad@hhsc.state.tx.us</a>
Actuarial Analysis	<a href="mailto:ActuarialAnalysis@hhsc.state.tx.us">ActuarialAnalysis@hhsc.state.tx.us</a>