Texas Vendor Drug Program
Drug Addition Process

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TEXAS Health and Human Services | Medical and Social Services

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1 About the Process

Texas Vendor Drug Program (VDP) staff review the Texas Drug Code Index (TDCI) Certification of Information (COI), the outpatient drug application, to ensure all federal and state requirements applicable to Medicaid and CHIP prescription drug benefits are met prior to a drug's addition to the TDCI.

Drugs must have a rebate agreement in place and certain high-cost drugs may require LBB approval prior to their addition to the TDCI.

In accordance with 2018-19 General Appropriations Act, S.B. 1, 85th Legislature, Regular Session, 2017 (Article II, Special Provisions Relating to All Health and Human Services Agencies, Section 17), drugs that are estimated to exceed $500,000 in annual General Revenue-related Funds or Temporary Assistance for Needy Families Federal Funds require approval from the LBB and the Governor, with the exception of drugs that are defined as orphan drugs.

Special Provision 17 has no LBB or Governor's approval requirement for the addition of orphan drugs to the TDCI; however, 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 initial analyses of new drugs no later than 30 days after receipt of the completed COI to ensure System Forecasting and HHSC Executive Leadership will have at least 60 days to complete the fiscal analysis and obtain LBB approval after completion of VDP analysis.
- VDP will alert System Forecasting sooner (at approximately Day 15 of the Clear Process) to new drugs that potentially may exceed the $500,000 threshold for LBB approval to provide that area more time to complete a fiscal impact, if possible.
- VDP will identify orphan drugs that qualify for coverage and add such drugs to the TDCI. Notification regarding a new or increased rate for orphan drugs will be submitted to the LBB and Governor within 60 days.

Questions or comments regarding this process should be submitted to vdp_formulary@hhsc.state.tx.us.

2 Formulary Drug Addition

2.1 Determining TDCI Eligibility

2.1.1 Begins Day 1

A completed COI is received from a drug manufacturer requesting addition of their drug to the TDCI. VDP will:

1. Check the Centers for Medicare & Medicaid Services (CMS) rebate file to determine if the drug has a rebate agreement:
   a. If the National Drug Code (NDC) is not on file, the process stops.
   b. If the NDC is on file, proceed to next step.
2. Determine if the drug is:
   a. Designated as an orphan drug by checking the U.S. Food and Drug Administration website at accessdata.fda.gov/scripts/opdlisting/oopd/. This page searches the Orphan Drug Product designation database. Searches may be run by entering the product name, orphan designation, and dates.
   b. Covered as a clinician administered drug (CAD) via the medical benefit:
      i. If not covered as a medical benefit, proceed to section 2.2 below.
      ii. If covered as a medical benefit, use clinical expertise to determine if the CAD is appropriate for distribution through a pharmacy:
         (1) If not appropriate for distribution through a pharmacy, the drug coverage will be handled as a medical benefit and not added to the TDCI (refer to section 3 below).
         (2) If appropriate for distribution through a pharmacy, proceed to section 2.2 below.

2.2 Estimate Number of People

The number of people that are eligible for Medicaid that may use the drug is estimated. The VDP pharmacist:

1. Checks the NDC package insert and review indications.
2. Researches compendia and/or clinical studies for information on epidemiology.

3. If applicable, in situations when a manufacturer replaces one NDC with another, performs a query of claim and encounter history to review utilization.
4. Checks the CMS website at medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html to see if other states have reported drug utilization data for the NDC. When available, the data includes state, drug name, NDC, number of prescriptions, and dollars reimbursed.
5. As needed, checks other sources, such as specialty pharmacies, manufacturers, and various foundations to gather additional information.
6. Determines if the drug needs a clinical prior authorization and develops the clinical criteria, as needed.
7. Uses clinical judgement and information gathered in the steps above to estimate the number of people enrolled in both fee-for-service and managed care who meet the criteria for coverage.

2.3 Estimate the Cost per Prescription

The cost per prescription is estimated. The VDP pharmacist:

1. Queries First Data Bank to obtain the National Average Drug Acquisition Cost or the Wholesale Acquisition Cost price.
2. If not available, gets the Average Wholesaler Pricing and the Net Cost to Wholesaler price from the COI.
3. Reviews the drug package insert, determines any requirements that might limit the quantity and/or duration of drug therapy, and calculates the maximum quantity allowed.
4. Calculates the estimated cost per prescription.

2.4 Estimate Fiscal Impact

2.4.1 Ends Day 30

The fiscal impact is estimated. The VDP pharmacist:

1. Performs the following calculations to determine the estimated cost:
   a. Estimated number of prescriptions: multiply the estimated number of people who may use the drug by the average number of prescriptions per year.

b. Estimated cost: multiply the estimated number of prescriptions by the cost per prescription.

2. Calculates the Federal Financial Participation and General Revenue (GR) of the estimated costs determined above.
3. For orphan drugs and any drug for which the estimated GR cost meets or exceeds $450,000 per state fiscal year, engages VDP Policy and System Forecasting staff for further evaluation:
   a. If the estimated GR cost falls below $450,000 per state fiscal year, then the drug is added within the allowable timeframes. Note: The dispensing fee is not included when estimating fiscal impact
   b. If there is any potential for a drug cost to exceed $500,000 per state fiscal year GR once added, the drug is referred for further analysis even if the estimated fiscal impact falls below $450,000 per state fiscal year GR.
   c. If identified as an orphan drug, the drug is added to the TDCI and VDP will coordinate with System Forecasting to prepare and submit the required orphan drug notification within 60 days, as required under Special Provision 17. LBB approval is not required for orphan drugs.

2.5 Fiscal Impact Analysis

2.5.1 Begins Day 31 if Cost Exceeds $500,000 per State Fiscal Year GR

A projected fiscal impact is completed to obtain rate approval for the drug's potential addition. System Forecasting:

1. Obtains necessary data to perform the analysis. Note: This is an interactive process with VDP staff to obtain drug pricing/dispensing fee data, rebate revenue data, potential drug cost offsets, and utilization assumptions. Other data collection is performed and varies by drug.
2. Completes gross drug cost projection analysis by calculating number of utilizers, cost per prescription, ingredient cost, and dispensing fee.
3. Calculates net drug cost by incorporating rebate revenue estimates for federal and supplemental (if applicable) rebates.
4. Calculates overall net cost impact after consideration of any potential cost offsets resulting from utilization of the drug under review.

2.6 Review of Fiscal Analysis

2.6.1 Ends Day 90, As Needed

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

1. Actuarial Analysis reviews to determine if the expected cost of the drug impacts managed care rates.
2. VDP and Actuarial Analysis determine payment methodology.
3. Actuarial Analysis determines if approval is needed by the Governor and LBB[1]. If approval is required, VDP and the Financial Services Division coordinate to obtain necessary approval.

3 Clinician Administered Drug Addition

Clinician administered drugs (CADs) are usually injectable or intravenous drugs, other than vaccines, administered by a medical professional in a physician's office or other outpatient clinical setting. CADs are reviewed as follows:

1. The federal Food and Drug Administration (FDA) approves a drug and a National Drug Code (NDC) is assigned.
2. The drug manufacturer obtains a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and Texas Medicaid is required to provide the drug benefit.
3. Because the drug does not have a unique procedure code, the claim will be submitted using the NDC and a miscellaneous J code.
4. The drug manufacturer submits an application to CMS for assignment of a Healthcare Common Procedure Coding System (HCPCS) code, and once assigned, the procedure code is received by the Texas Medicaid program on either the annual or a quarterly HCPCS update from CMS.
5. Once CMS assigns a HCPCS code and the code is received by Texas Medicaid, the Medicaid and CHIP Services Medical Policy team begins

[1] Pursuant to the 2016-2017 General Appropriations Act, House Bill 1, 84th Legislature, Regular Session, 2015 (Article II, Special Provisions Relating to All Health and Human Services Agencies, Section 43).

research to determine coverage criteria for the drug. At this time, the drug is also referred by Medical Policy to HHSC Rate Analysis for the fee-for-service (FFS) HCPCS interim rate process. The HCPCS interim process includes:

a. The VDP analyst estimates the cost per person or per dose.
b. Rate Analysis researches implications of the 2016-17 General Appropriations Act, H.B. 1, 84th Legislature, Regular Session, 2015 (Article II, Special Provisions Relating to All Health and Human Services Agencies, Sec. 43).
    i. If the fiscal impact to General Revenue (GR) is greater than $500,000 per SFY, a determination is made by the Executive Commissioner on whether Legislative Budget Board (LBB)/Governor approval will be pursued, or whether the agency will provide notification as required by Sec. 43 for HCPCS updates. If the agency seeks LBB/Governor approval, HHSC informs the LBB of the requested effective date, but the drug cannot be reimbursed until receipt of LBB approval.
    ii. If the fiscal impact to GR is less than $500,000 per SFY, the interim rate process would be implemented and the HCPCS code(s) would become effective to match the CMS effective date. Notification would be included in the next quarterly report also required by Sec. 43.
c. Letters to the LBB/Governor, if applicable, are submitted for Executive Commissioner approval by the Deputy Executive Commissioner for Financial Services. The Quarterly Report to the LBB/Governor is prepared by Rate Analysis Department. Note: The interim rate is reviewed by Rate Analysis at the next CADs rate review and adjusted as needed.

6. Once the drug has a unique code, Medicaid and CHIP Services Medical Policy is able to assign specific coverage criteria, including prior authorization, to the unique HCPCS code.