Texas Vendor Drug Program
Specialty Drug List Process

February 2019

TEXAS
Health and Human Services
Medical and Social Services

Table of Contents

1 About the Specialty Drug List

HHSC defines a specialty drug as one that meets all four of the criteria of the Specialty Drug rule (1 TAC Section 354.1853). The specialty drug list (SDL) identifies all drugs that meet these criteria. The SDL is published quarterly by the Texas Vendor Drug Program.

The SDL and other related documents mentioned within this document are published on the Vendor Drug Program website:

- https://www.txvendordrug.com/formulary/formulary/specialty-drugs

Questions or comments about the SDL should be sent by email:

- VDPPharmacyOperations@hhsc.state.tx.us

1.1 Information for Pharmacies

- Any Medicaid-enrolled pharmacy can dispense a drug identified on the SDL for people enrolled in traditional Medicaid.
- A pharmacy may need to enroll in a managed care health plan's specialty pharmacy network to dispense a drug identified on the SDL.

1.2 Information for Managed Care Organizations

- Texas Government Code §533.005(a)(23)(G), as added by Section 1.02(d), Senate Bill 7, 82nd Legislature, First Called Session, 2011, requires Medicaid managed care organizations and subcontracted pharmacy benefit managers to adopt policies and procedures for reclassifying prescription drugs from retail to specialty drugs that are consistent with rules adopted by the HHSC Executive Commissioner.
- The only drugs that may be exclusively provided through the MCO's specialty pharmacy network are those drugs listed on the SDL.
- MCOs will have three months after a drug is removed from the published SDL to adjust contracts.

1.3 Information for Prescribing Providers

- Prescribing providers may be asked to send prescriptions for drugs on the SDL to a health plan's specialty pharmacy network.
- Some drugs identified on the SDL may require clinical and/or non-preferred prior authorization.

2 Criteria Review

A drug qualifies for inclusion on the SDL it must meet all four of the criteria of the Specialty Drug rule:

1. The drug is used to treat and is prescribed for a person with a complex, chronic, or rare medical condition that is progressive, can be debilitating or fatal if left untreated or undertreated, or for which there is no known cure.
2. The drug is not routinely stocked at a majority of community retail pharmacies.
3. The drug has special handling, storage, inventory, or distribution requirements.
4. Patients receiving the drug require complex education and treatment maintenance, such as complex dosing, intensive monitoring, or clinical oversight.

2.1 Medical Condition

A drug will meet this rule criteria if the drug is to treat and is prescribed for a person with a complex, chronic, or rare medical condition that is:

- Progressive; or
- Debilitating or fatal if left untreated or undertreated; or
- Has no known cure.

2.2 Stocking

HHSC evaluates a drug for inclusion on the SDL after the drug has been on the Medicaid formulary for at least six months. A claim utilization report will identify all pharmacy types that dispensed each drug in Medicaid (both traditional and managed care).

A drug will meet this rule criteria if the utilization report identifies specialty pharmacies are the type of pharmacy dispensing the drug at least 70% of the time.

2.3 Special Handling or Storage

HHSC reviews the information submitted by the drug manufacturers on the Texas Drug Code Index Certification of Information (HHS Form 1326). The manufacturer identifies if the drug meets any of the following specifications:

1. The manufacturer allows only specific pharmacies or pharmacy chains to dispense the drug
2. The drug needs to be administered within less than 48 hours after dispensing
3. Requires protective handling (e.g. hazardous drugs with mutagenic, carcinogenic, teratogenic or adverse reproductive effects, or requires laminar flow hoods for preparation or mixing)
4. Requires aseptic techniques for compounding in accordance with federal and state standards
5. Requires the patient to receive specific labs for therapeutic efficacy, toxicity, or physiological testing (e.g. renal function, liver enzyme tests, complete or partial blood counts) at baseline and during or post-drug treatment
6. Requires highly-specialized storage equipment or facilities that are not commonly available in retail pharmacies (e.g. more than just refrigeration)

2.4 Special Education and Treatment Maintenance

HHSC staff pharmacists will use professional judgment to identify if the drug meets both of the following specifications:

1. Do patients using the drug require complex education to promote appropriate utilization of the drug or is there a need to educate on proper storage, preparation, and administration?
2. Do patients using the drug require treatment maintenance, such as complex dosing, intensive monitoring, or clinical oversight?

3 Public Comment

Each quarter HHSC staff pharmacists review drugs that meet the rule criteria. This resulting list will be published on the Vendor Drug Program website as that quarter's draft SDL.

HHSC welcomes comments from pharmacy staff, MCO staff, and medical and other external stakeholders regarding the draft SDL. Stakeholders are given 10 business days from the publication of the draft document to propose additions to or removals from the draft SDL using the Specialty Drug Submission Spreadsheet.

- Requests received outside the 10-business-day review period are kept and reviewed during the next quarterly review
- HHSC provides an initial acknowledgement and additional follow-up on whether the proposal was accepted or denied

A final SDL, incorporating approved public comment, is published each quarter.

3.1 Submission Spreadsheet

The SDL Submission Spreadsheet is available from the website at https://www.txvendordrug.com/formulary/formulary/specialty-drugs. The document contains four tabs.

3.1.1 Contact Tab

The following information is requested on the Contact tab of the submission spreadsheet:

- Date of submission
- Name of person submitting request
- Name of organization
- Email address and contact phone number
- The calendar year and quarter of the SDL recommendation
  - Refer to Table 2, below, for the quarter timelines.

3.1.2 Criteria Tab

A copy of the four SDL criteria are included as reference.

3.1.3 Layout Tab

The layout tab is a reference of the fields required for submission on the Submit tab. The fields identified in Table 1 are required for HHSC staff to consider the submission.

Table 1: Fields for Stakeholder Submission

Column	Field	Description
A	NDC	11-digit national drug code number
B	Drug name	Name of product
K	Criteria #1 Justification	Stakeholder provides detailed explanation of how NDC does or does not meet all of criteria #1
M	Criteria #3 Justification	Stakeholder provides detailed explanation of how NDC does or does not meet all of criteria #3
N	Criteria #4 Justification	Stakeholder provides detailed explanation of how NDC does or does not meet all of criteria #4
O	Final Recommendation Status	Stakeholder identifies one of the two selections: • Add: meets the 3 criteria on this document • Remove: does not meet at least 1 criteria on this document

3.1.4 Submit Tab

The following information is requested on the Submit tab of the submission spreadsheet:

- 11-digit national drug code number (column A)
- Name of product (column B)

- A detailed explanation how the drug does or does not meet criteria #1 (column K), criteria #3 (column M), and criteria #4 (column N).
  - Justification should explain the drug's complex education or treatment maintenance and list the name (and NPI, if known) of the pharmacies limited to dispensing the drug.
  - Simply identifying a drug "meets" or "does not meet" criteria is not sufficient and such submittals will be returned citing not enough information.
- The stakeholder should identify the final recommendation status (column O) as either one of the two selections:
  - Add
    - Meets the 3 criteria on this document
  - Remove
    - Does not meet at least 1 criteria on this document
- Stakeholders should add new rows to the document as needed.

Stakeholders can manually enter drug information into this tab or copy a specific row from a published SDL.

3.2 Submission to HHSC

Stakeholders should save a copy of the spreadsheet locally, and their completed file should be sent to HHSC by email at VDPPharmacyOperations@hhsc.state.tx.us.

4 Schedule

The dates in Table 2 identify when events in the specialty drug list process occur during the state fiscal year.

Table 2: Specialty Drug List Schedule

CY Quarter	HHSC Work Begins	Draft Published / Public Comment	Final Published
Q1 (Jan-Mar)	Jan.	Feb.	Mar.
Q2 (Apr-Jun)	Apr.	May	Jun.
Q3 (Jul-Sept)	Jul	Aug.	Sept.
Q4 (Oct-Dec)	Oct.	Nov.	Dec.