Texas Children's	Clinician Administered Drug Guideline	
Guideline # 10141	***Categories*** Administration / Non-Clinical →TCHP - Administration	***This Guideline Applies To:*** Texas Children's Health Plan ***Document Owner*** Lisa Fuller

GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) performs authorization on certain clinician-administered drugs (CADs) including ALL clinician-administered drugs reimbursed with a non-risk payment methodology, high cost at-risk CADs and all clinician-administered drugs that are not covered per the NDC-to-HCPCS Crosswalk.

For services surrounding unclassified drugs and/or high-cost medical drugs without a permanent designated HCPCS code, TCHP Utilization Management (UM), in partnership with TCHP Pharmacy Department, reserves the right to review these drugs for clinical necessity. This includes a review for clinical appropriateness and safety based on the Food and Drug Administration (FDA) labeled indication(s) and/or associated clinical trials to determine the most appropriate response to the medication inquiry. Requests will be subject to review on a case-by-case basis factoring in the risk versus benefit, as well as all pertinent available information (e.g., information provided by Utilization Management personnel including but not limited to: member's current disposition, inpatient or outpatient use, among other details) to determine a response.

DEFINITIONS:

Clinician Administered Drugs: Clinician-administered drugs or biologicals are medications given by injection or infusion in the home, office or outpatient clinic setting when oral medications are not appropriate. This includes any active drug on the Clinician Administered drug index published by the Texas Vendor Drug Program. These medications are typically injectable medications given in an office or outpatient clinic setting and billed through the medical benefit CADs are also known as "medical drugs" or "physician administered drugs."

Clinician administered drug (CAD) index: A list of covered CADs approved for medical billing by the Texas Vendor Drug Program and updated quarterly. This is also known as the "medical drug formulary" or "NDC/HCPCS crosswalk."

Non-Risk Clinician-Administered Drugs: Clinician-administered drugs reimbursed under the medical benefit that are not included in MCO capitation rates. These drugs are identified in Uniform Managed Care Manual Chapter 2.0, "Clinician-administered Drugs Covered Under Non-Risk

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

Payment". These medications designated by Texas Health and Human Services to pay on a non-risk cost settlement basis in accordance with Section 10.18 of the Uniform Managed Care Contract ("Non-Risk Payments of Drugs"). The state will provide 100% reimbursement for the cost of the drug, while the drug holds "non-risk" status (not including administrative and/or ancillary costs).

Healthcare Common Procedure Coding System (HCPCS): Collection of standardized codes that represent medical procedures, supplies, products, and services that are used to facilitate the processing and/or billing of claims by insurers.

High-cost Medical Drug: Medication with a procedure code and/or HCPCS code with billed charges to TCHP greater than or equal to $5,000 (USD).

Unclassified Drug: Medications with a temporary or unassigned HCPCS code. Some may include, but are not limited to: J3490, J3590, C9399, J9999.

Prior authorization will not be required for high cost J3490 claims under $5,000 (USD). The provider or office will need to submit a "pre-service" prior authorization for payment approvals for any J3490 medical claims which equal or exceeds $5,000 (USD) "Billed to Plan."

Any claims for the other unclassified codes (J3590, C9399, J9999) will require a pre-service authorization regardless of the billed charges.

Clinical appropriateness will be determined by assessing various resources, including but not limited to: FDA package insert, clinical trials, primary, secondary, and tertiary literature, drug's indicated use, approved patient population, inclusion/exclusion criteria, among other factors.

NDC-to-HCPCS Crosswalk: Identifies relationships between National Drug Codes (NDC) and Medicaid-payable Healthcare Common Procedure Coding System (HCPCS) codes. The crosswalk assists with billing and coding and is a reference for converting HCPCS billing units to valid NDC unit calculations. The crosswalk is published quarterly and based on revisions to the CMS list of rebate-eligible drugs and new drugs and biologicals added to First Databank.

GUIDELINE

1. All requests for prior authorization of clinician-administered drugs are received via online submission, fax, phone or mail by the Utilization Management Department and processed during normal business hours.

2. The prior authorization request must include:
    - 2.1. Documentation for medical necessity of the equipment or supplies requested
    - 2.2. Procedure codes or HCPCS codes requested

2.3. Numerical quantities for services requested

2.4. Documentation of the member's dosage

2.5. Administration schedule

2.6. Number of doses to be administered during the prior authorization period

2.7. Requested units per injection or infusion

2.8. The dosage calculation must be submitted in Section C of the Special Medical Prior Authorization (SMPA) Request Form under Statement of Medical Necessity

2.9. The requesting provider may be asked for additional information to clarify or complete a request

3. The Utilization Management professional reviewing the request evaluates the submitted information to determine the medical necessity of the requested clinician-administered drug.

4. Clinician-administered drugs will be subject to the prior authorization requirements, medical necessity criteria and limitations defined by the current Texas Medicaid Provider Procedures Manual (TMPPM), Outpatient Drug Services Handbook.

5. Requests for clinician-administered drugs will be reviewed by a TCHP Medical Director/Physician Reviewer for medical necessity when:

   5.1 Prior authorization requirements or medical necessity criteria in TMPPM, Outpatient Drug Services Handbook are not met

   5.2 Medical necessity criteria is not defined in the current Texas Medicaid Provider Procedures Manual, Outpatient Drug Services Handbook

   5.3 Drug is classified as non-risk

   5.4 Billed charges are $5000 or more

   5.5 Code for the drug is unclassified. This includes but is not limited to J3490, J3590, C9399, J9999.

6. Providers are responsible for administering drugs based on the U.S. Food and Drug Administration (FDA)-approved guidelines. In the absence of FDA indications, the following criteria must be met:

   6.1 The drug is recognized by the American Medical Association Drug Evaluations (AMA-DE), American Hospital Formulary Service Drug Information, the U.S. Pharmacopoeia Dispensing Information, Volume I, or two articles from major peer-reviewed journals that have validated and uncontested data supporting the proposed use for the specific medical condition as safe and effective.

   6.2 It is medically necessary to treat the specific medical condition, including life-threatening conditions or chronic and seriously debilitating conditions

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

6.3. The off-label use of the drug is **NOT** investigational or experimental.

7. All authorization requests for clinician-administered drugs reimbursed with a non-risk payment methodology, unclassified code or with billed charges of $5000 or more will be reviewed by a TCHP Medical Director/Physician Reviewer to determine medical necessity.

8. Non-FDA approved clinician-administered drugs are not a benefit.
9. Drugs requested for use outside of FDA approved indications is considered experimental and investigational and as such are not covered. Experimental and investigational services are not covered by Texas Medicaid. Medical Director review is required for consideration of approval on a case by case basis.
10. Oral medications that are given in the hospital or physician's office are considered part of the hospital or office visit and cannot be reimbursed separately.

11. Drugs and biologicals whose manufacturers do not participate in the Center for Medicaid Services (CMS) Drug Rebate Program, do not show as active on the CMS list for the date of service the drug is administered, and/or do not have a rebate eligible National Drug Code (NDC) are not a benefit.

12. Refer to Case-by-Case Added Services Policy and Case-by-Case Added Services Procedure for consideration of any requests that may not meet guideline criteria. All requests that do not meet guideline criteria require Medical Director review.

13. Requests for Monoclonal Antibody administration will follow the TCHP Monoclonal Antibodies Guideline #11062

14. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

Related Documents:

Unclassified Drug High-Cost Threshold Procedure, Procedure #11979

REFERENCES:

Government Agency and Medical Society, and Other Publications:

Texas Medicaid Provider Procedures Manual Volume 2, Outpatient Drug Services Handbook, Section 2: Clinician-Administered Drugs. Accessed March 9, 2025

https://www.tmhp.com/sites/default/files/file-library/resources/provider-manuals/tmppm/pdf-chapters/2025/2025-03-march/2_15_outpatient_drug.pdf

NDC-to-HCPCS Crosswalk. Published quarterly. Accessed March 9, 2025

https://www.txvendordrug.com/formulary/clinician-administered-drugs

Uniform Managed Care Manual Chapter 2: Texas Claims Procedures Section 2.0 Claims Manual Version 2.14 Accessed March 9, 2025

https://www.hhs.texas.gov/sites/default/files/documents/laws-regulations/handbooks/umcm/2-0.pdf

Status	Date	Action
Approved	3/13/2025	Clinical & Administrative Advisory Committee Reviewed and Approved for Implementation

Original Document Creation Date: 08/29/2019	This Version Creation Date: 08/21/2024	Effective/Publication Date: 08/29/2024

Printed copies are for reference only. Please refer to the electronic copy for the latest version.