An Important Message from

The Texas Health and Human Services Commission (HHSC)

Alternative Coverage of Omnipod 5 Through Medical Benefit

Background:

The Texas Health and Human Services Commission (HHSC) is aware that the Eros/Classic Omnipod Insulin Management System model is discontinued to new users. In addition, the related supplies and accessories are only available to existing clients through the current Durable Medical Equipment (DME) medical benefit process through Dec. 31, 2023.

The Insulet Corporation which manufactures Omnipod has created and marketed the new Omnipod 5 for individuals with type I diabetes with the restriction that it is only available through retail pharmacies. Since November 2022, HHSC is seeking approval from the Centers for Medicare and Medicaid Services (CMS) to provide coverage of non-drug products such as Omnipod on the Vendor Drug Program (VDP) formulary. Upon CMS approval, HHSC will complete the process of adding Omnipod 5 to the VDP formulary. While HHSC continues to work with CMS and is seeking an expedited review, it is possible that CMS will not provide approval and VDP will not be able to add Omnipod 5 to the VDP formulary by Dec. 31, 2023. **UnitedHealthcare Community Plan of Texas (UHC)** may not cover Omnipod 5 through the pharmacy benefit until VDP can add it to the formulary.

Key Details:

HHSC has identified an alternative method of coverage to ensure Medicaid members have access to Omnipod 5 after Dec. 31, 2023, if CMS approval is not received before Jan. 1, 2024. HHSC requires **UHC** to provide all medically necessary services under Early, Periodic, Screening, Diagnostic, Testing (EPSDT), also known as Texas Health Steps, or under the “Home Health DME and Supplies Exceptional Circumstances” (Exceptional Circumstances) policy. In the event CMS approval is not received for Omnipod 5 before Jan. 1, 2024, **UHC** will cover it as an EPSDT service or under the Exceptional Circumstances policy no later than Jan. 1, 2024, for eligible members.

EPSDT – For 20 Years and Younger

Section 1905(r) of the Social Security Act mandates that all Medicaid-eligible beneficiaries age 20 and younger receive medically necessary services to treat, correct and ameliorate illnesses and conditions identified in an EPSDT screening for a service that is not included in the state’s Medicaid plan or goes beyond the limits of the state plan or Texas Medicaid Provider Procedures Manual (TMPPM), but is allowable by CMS. These services must be covered under EPSDT. EPSDT does not apply to the Children’s Health Insurance Program or Medicaid members 21 and older. Omnipod 5 qualifies for inclusion as a medical benefit through EPSDT. See below notices on EPDST and Section 8.2.2.3 of the Uniform Managed Care Contract (UMCC).

Note: UnitedHealthcare Community Plan of Texas (UHC) replaced MCO in original notice from HHSC.

Exceptional Circumstances – For 21 Years and Older

The Exceptional Circumstances policy is in accordance with Title 42 Code of Federal Regulations (CFR) §440.70(b)(3)(v) and Title 1 TAC Section 354.1039(a)(4)(D). Under the Exceptional Circumstances, Texas Medicaid is obligated to consider coverage of medically necessary DME and supplies that are not currently listed as benefits of Texas Medicaid for clients who are 21 years or older. Omnipod 5 qualifies for inclusion as a medical benefit through the Exceptional Circumstances policy. See previous notices on Exceptional Circumstances below and TMPPM Section 2.2.3 for more details about this policy.

Coverage Details

Omnipod 5 is distributed only through retail pharmacies. However, EPSDT and Exceptional Circumstances allow coverage of non-drug products, including Omnipod 5, as a medical benefit. **UHC** will identify retail pharmacies that are also enrolled DME providers that may dispense Omnipod 5 and bill through the medical benefit. Pharmacies may not bill Omnipod 5 as a pharmacy benefit until HHSC adds it to the formulary following CMS approval. **UHC** pharmacy directors will collaborate with our medical benefit partners to follow the **UHC's** existing EPSDT process.

Existing Omnipod Eros/Classic users are allowed access to the updated Omnipod models through the ESPDT and the Exceptional Circumstances policy by waiving the three-year device replacement waiting period due to lack of availability of supplies for the original model.

See Medical Benefit billing details below:

The alternative tubeless external insulin pump (Omnipod) should be billed using the external insulin pump code E0784 with a U1 modifier and A9274 for its disposable pod including all supplies and accessories.

HHSC will immediately inform **UHC** if Omnipod 5 becomes available on the formulary and the alternative method of coverage process is no longer necessary.

Resource Documents Below:

- Home Health Durable Medical Equipment and Supplies Exceptional Circumstances Provision Questions and Answers
- Home Health Durable Medical Equipment and Supplies Exceptional Circumstances Provision
- Coverage of Services Not in the TX-MCD SP
- 2020 1214 - Services Not Covered in the Texas Medicaid State Plan

Questions?

Please contact your physician advocate or call UnitedHealthcare Provider Services at 888-887-9003, 8 a.m.–6 p.m. CT, Monday–Friday.

Note: UnitedHealthcare Community Plan of Texas (UHC) replaced MCO in original notice from HHSC.

Home Health Durable Medical Equipment and Supplies Exceptional Circumstances Provision Questions and Answers:

1. *Unlike children's Medicaid where we authorize these on the basis of MN as stipulated in the EPDST provision to include all services eligible for FFP, these services are optional in federal law (not mandatory) for adults, and FFP is typically limited to items covered under the state plan – based on this, what criteria are the MCOs to use to determine if the item being authorized is eligible for FFP?*

   The Code of Federal Regulations categorizes Medicaid services as either required or optional. Durable medical equipment is categorized as a required service. Under the CFR states may create a list of pre-approved DME but may not have absolute exclusions. Instead states must have a process for requesting items not on the state's approved list. This part of the CFR – Title 42 Chapter 440 – is not limited to children, and it is this part of the regulation that HHSC is following.

2. *Additionally, how should services be submitted on encounters and how will these items be captured in the FSR and rate setting process for reimbursement to the plans?*

   For the time being, DME and supplies provided under this provision may need to be reimbursed using miscellaneous DME codes. HHSC is working on a modifier or other identifier can be put in place to allow for better reporting and tracking of these expenditures. Please note that providers should request items of DME with the most appropriate code even though there may be a need to bill with a miscellaneous code.

3. *Often provider contracts are written to pay a certain percentage of a rate for miscellaneous codes. What can be done to allow providers to be reimbursed at the full rate?*

   HHSC suggests following the same process used to reimburse EPSDT services not covered under the state plan.

4. *How are MCOs to discern if the items should be covered by a waiver or through this exception process?*

   Reimbursement under a 1915(c) or 1915(c)-like waiver is always the last resort. HHSC is putting together a comprehensive crosswalk of adaptive aids covered through waivers and how the waiver policies interact with the exceptional circumstance policy.

5. *How will this be reconciled in the UMR and OIG audits to ensure we do not get ding for coverage of an item that is not outlined in the state plan?*

This policy is consistent with state and federal regulations. We will be adding these clarifying requirements to the UMCM, which will also provide support to the MCOs. HHSC will coordinate with OIG to ensure they are aware of and understand the exceptional circumstances policy.

6. *Does the exceptional circumstances process apply to prescription drugs?*

   No.

7. *Could we get an example of an exception like DME that could not be considered an exception for an adult even if medically necessary?*

   Under 42 CFR §440.70(b)(3)(v), states may not have absolute exclusions of coverage on medical equipment, supplies, or appliances. States must have processes and criteria for requesting medical equipment that is made available to individuals to request items not on a State's preapproved list.

12/10/2020

Home Health Durable Medical Equipment and Supplies Exceptional Circumstances Provision

Background:

Texas Medicaid's obligation to consider coverage of medically necessary Durable Medical Equipment (DME) and supplies not otherwise covered as a Texas Medicaid benefit for clients 21 years of age and older is known as the home health DME and supplies exceptional circumstances provision ("exceptional circumstances").

Under 42 Code of Federal Regulations (CFR) §440.70(b)(3)(v), states must have a process that uses reasonable and specific criteria to assess items for coverage and criteria for requesting medical equipment, including items listed as non-covered services in the Texas Medicaid Provider Procedures Manual (TMPPM) and any other DME and supplies that are not already a benefit of Medicaid. The exceptional circumstances provision complies with 42 Code of Federal Regulations (CFR) §440.70(b)(3)(v), and 1 Texas Administrative Code (TAC) §354. 1039(a)(4)(D). Additionally, a requirement for MCOs to deliver home healthcare services in accordance with 42 C.F.R. §440.70 was added to managed care contracts in September 2018.

Key Details:

In accordance with Chapter 16 of the Uniform Managed Care Manual (UMCM) and the Uniform Managed Care Contract (UMCC), MCOs must provide all medically necessary Medicaid-covered services and benefits in the same amount, duration, and scope as is available through fee-for-service (FFS) as reflected in the Texas Medicaid State Plan and detailed in the TMPPM. (UMCM Section 16.1.2.22 and UMCC Section 8.1.2)

There is no exhaustive list of Medicaid-covered DME and supplies. Rather, 42 CFR §440.70(b) (3)(v) provides a general description of allowable items. Based on this regulation, allowable items include medical supplies, equipment, and appliances suitable for use in any setting in which normal life activities take place.

Supplies are health care related items that are consumable, disposable, or cannot withstand repeated use by more than one individual, that are required to address an individual medical disability, illness or injury.

Equipment and appliances are items primarily and customarily used to serve a medical purpose, generally not useful to an individual in the absence of a disability, illness or injury, can withstand repeated use, and can be reused or removed.

If a member requests an item that could be described as a supply, equipment, or an appliance using these parameters, but is not included as a Texas Medicaid covered item, the MCO should pursue coverage under the exceptional circumstances process. Examples of such items include:

- Augmentative communication device (ACD) systems
- bath and bathroom equipment
- bone growth stimulators
- diabetic equipment and supplies
- hospital beds and equipment
- incontinence supplies
- IV supplies and equipment
- mobility aids
- nutritional (enteral) products, supplies and equipment
- PT/INR monitors and related testing supplies
- wound care equipment and supplies

Effective June 1, 2020, the TMPPM was updated with information on operationalizing the exceptional circumstances provision for Medicaid clients 21 years of age and older.

Providers must submit requests for medically necessary DME and supplies not listed as a covered benefit under Texas Medicaid to the member's MCO through the exceptional circumstances process such as the process outlined in the TMPPM. This process is limited to DME and supplies permitted under federal Medicaid rules.

DME and supplies allowed under the exceptional circumstances provision must be prior authorized by the MCO.

Attached are related FAQs that MCOs may find helpful.

Resources:

Home Health Durable Medical Equipment and Supplies Exceptional Circumstances Provision Questions and Answers (Attached)

Contact:

Eileen.Murphy@hhs.texas.gov

Attachment:

Home Health Durable Medical Equipment and Supplies Exceptional Circumstances Provision Questions and Answers.pdf

Type: Informational

To: CHIP; STAR; STAR+PLUS; STARHEALTH; STAR_KIDS

From: Policy

TEXAS Health and Human Services

Coverage of Services Not in the Texas Medicaid State Plan

In some cases, Texas Medicaid Managed Care Organizations (MCOs) cover services that are not included in the Medicaid State Plan.

These services fall into specific categories: services covered due to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT), in-lieu-of services, case-by-case services, value-added services, medically necessary Centers for Medicare and Medicaid Services (CMS)-covered outpatient drugs not yet on the Texas Medicaid formulary, and durable medical equipment (DME) covered under the Home Health DME and Supplies Exceptional Circumstances provision.

Below is an overview of these categories, followed by a chart with cited sources for this information.

Services covered due to EPSDT

- Section 1905(r) of the Social Security Act mandates that all Medicaid eligible beneficiaries age 20 and younger receive medically necessary services to treat, correct and ameliorate illnesses and conditions identified in an EPSDT screening, if the service is covered in the state's Medicaid plan or if the service is allowable as a Medicaid state plan benefit by CMS.
  - Exceptions include: experimental or investigational treatment, services or items not generally accepted as effective and/or not within the normal course and duration of treatment, and services for the caregiver or provider convenience.
- In Texas, this is known as the Texas Health Steps Comprehensive Care Program (CCP).
  - If a Medicaid member, age 20 or younger, is screened through THSteps and determined to have medical necessity for a service that is not included in the Texas Medicaid State Plan or goes beyond the limits of the State Plan or Texas Medicaid Provider Procedures Manual, but is allowable by CMS, then those services must be covered under EPSDT.
  - Providers must submit prior authorization and supporting documentation when requesting a medically necessary service if the service is not

addressed in the Texas Medicaid Provider Procedures Manual (TMPPM) and the client is 20 years of age or younger.
  - Services covered under EPSDT are included in the rate setting process.

In-lieu-of services

- In-lieu-of services are not covered in the Medicaid State Plan but are offered in lieu of a covered service or setting. In-lieu-of services must be approved by HHSC and are outlined in MCO contracts listed in the table below. In-lieu-of services are included in the rate setting process.
- Allowable in-lieu-of services in Texas are inpatient mental health care provided at an institution for mental disease (IMD) in lieu of an acute care hospital for members ages 21-64, certain services in chemical dependency treatment facilities for substance use disorder treatment in lieu of an acute care hospital.
  - As part of the implementation of SB 1177, 86th Legislature, Regular Session, 2019, HHSC is evaluating additional evidence-based behavioral health services for cost-effectiveness to be offered in-lieu-of existing state plan services when medically appropriate. HHSC anticipates corresponding contract amendments to be effective in state fiscal year 2021.

Case-by-case services

- MCOs may offer individual members additional benefits that are outside the scope of services. These services may be based on medical necessity, cost-effectiveness, the wishes of the member or the member's family, or the potential for improving the member's health status. For STAR+PLUS, STAR Kids, and STAR Health members, these case-by-case services may also be based on functional necessity.
- Case-by-case services are not included in the rate-setting process and do not require HHSC approval. MCOs may choose to offer case-by-case services in appropriate situations to any of their members but are not required to do so. MCOs often choose to provide case-by-case services for a variety of reasons such as improvement of health status or cost-effectiveness.
- MCOs may use current capitation to provide case-by-case services, but case-by-case services may not be included in encounter data for future rate setting processes. Case-by-case services and benefits cannot increase the cost borne or capitation rates paid by HHSC and cannot violate any other state or federal rule or regulation. The MCO must maintain documentation of each authorized case-by-case service provided to each member.

Value-added services

- Value-added services or benefits are additional services proposed by MCOs, within specified programs and service areas, and generally available to all members who meet the MCO's qualification criteria for the service.
  - Value-added services may be actual health care services, benefits, or positive incentives that HHSC determines will promote healthy lifestyles and improved health outcomes among members. Best practice approaches to delivering covered services are not considered value-added services.
- These services and benefits must be approved by HHSC.
- Any value-added services that MCOs elect to provide must be provided at no additional cost to HHSC.
  - The costs of value-added services are not reportable as allowable medical or administrative expenses, and therefore are not factored into the rate setting process.
  - Value-added services must be included in encounter data and are designated with Financial Arrangement Code (FAC) '11'.
- In addition, MCOs may not pass on the cost of the value-added services to members or providers.

Medically necessary CMS-covered outpatient drugs not yet on the Texas Medicaid formulary

- MCOs must cover CMS-covered outpatient drugs not yet on the Vendor Drug Program formulary if the drugs are medically necessary and prescribed by a qualified provider. CMS-covered outpatient drugs not yet on the Vendor Drug Program formulary are included in the rate-setting process.
- Drugs that are not federally rebateable may be covered for members 20 years and younger under EPSDT. For members 21 years and older, MCOs may offer coverage to individual members as a case-by-case service.

DME covered under the Home Health DME and Supplies Exceptional Circumstances provision

- The Home Health DME and Supplies Exceptional Circumstances provision, a requirement for MCOs to deliver home healthcare services in accordance with 42 Code of Federal Regulations (CFR) §440.70, was added to the managed care contracts listed in the table below in September 2018. DME provided under this provision of the CFR are included in the rate setting process.
- Additional information about DME covered under the home health DME and supplies exceptional circumstances provision is available in the MCO Notice

titled, "Home Health Durable Medical Equipment and Supplies Exceptional Circumstances Provision" and delivered on December 10, 2020.

Federal Authority	State Authority	Description
Services covered due to EPSDT		
Section 1905(r)(5) of the Social Security Act	• Uniform Managed Care Contract (UMCC), STAR+PLUS Expansion, STAR+PLUS MRSA, STAR Health, and STAR Kids Contracts, Attachment A • TMPPM Children's Services Handbook, Section 2, "Medicaid Children's Services Comprehensive Care Program (CCP)"	Services that are not covered by the Texas Medicaid State Plan but are considered an allowable service by CMS may be covered due to EPSDT if medical necessity criteria are met. The only time a service for members under 21 would not be considered for coverage under EPSDT is if the service was not considered an allowable service by CMS.
In-lieu-of services		
42 CFR §438.3(e)(2)	• Texas Government Code § 533.005(g) • UMCC ▸ Attachment B-2, ▸ Attachment B-2.2 ▸ 8.1.15.7.1, "Psychiatric Services" • STAR+PLUS Expansion, STAR+PLUS MRSA, and STAR Health Contracts, ▸ Attachment B-2 ▸ 8.1.15.7.1, "Psychiatric Services" • STAR Kids Contract, Attachment B-2 • Section 1115 demonstration waiver, "Texas Healthcare Transformation and Quality Improvement Program"	A service or setting that is not covered in the state plan and offered in lieu of a covered service or setting. In Texas, allowable in lieu of services are services provided in Institutions of Mental Diseases (IMDs) in lieu of acute care hospitals, and certain services in chemical dependency treatment facilities for substance use disorder treatment in lieu of acute care hospitals.
Case-by-case services		
42 CFR §438.3(e)(1)	• 1 Texas Administrative Code (TAC) §353.409 • UMCC, STAR+PLUS Expansion, STAR+PLUS MRSA, and STAR Health Contracts, 8.1.2.2, "Case-by-Case Services"	A service that is not covered in the state plan or by EPSDT, does not have to be approved by HHSC, and does not have to be provided to all MCO members. Case-by-case

Federal Authority	State Authority	Description
	• STAR Kids Contract, §8.1.2.4, "Case-by-Case Services"	services may include services and benefits that are not otherwise covered by Texas Medicaid. Case-by-case services are not included in the capitation rate.
Value-added services		

42 CFR §438.3(e)(1)	• 1 TAC §353.409;
	• UMCC, STAR+PLUS Expansion
	• STAR+PLUS MRSA, and STAR Health Contracts
	  ▸ Attachment A
	  ▸ §8.1.2.1, "Value-added Services"
	• STAR Kids Contract,
	  ▸ Attachment A
	  ▸ §8.1.2.3, "Value-added Services"
		A service that is not covered in the state plan and offered by an MCO to all of their members who meet the eligibility criteria for the service in a specific MCO program and service area. Examples include car seats and bike helmets.

Medically necessary CMS covered outpatient drugs not yet on the Texas Medicaid formulary (pharmacy)		
42 USC §1396r-8(a)(1), (k)(2); 42 CFR §438.3(s)	• 1 TAC §353.905(a) • Uniform Managed Care Manual (UMCM) Chapter 2.2, Section I, "Medically Necessary Non-Formulary Drug" • UMCC §8.1.21, "Pharmacy Services" • STAR+PLUS Expansion Contract, §8.1.42, "Pharmacy Services" • STAR+PLUS MRSA Contract, §8.1.16, "Pharmacy Services" • STAR Kids Contract, §8.1.17, "Pharmacy Services" • STAR Health Contract, §8.1.20, "Pharmacy Services"	CMS-covered outpatient drugs not yet on the formulary must be approved by MCOs if medically necessary and prescribed by a qualified provider. These drugs are included in the rate-setting process because federal regulation requires HHSC to pay for them.
DME covered under the Home Health DME and Supplies Exceptional Circumstances provision		
42 CFR §440.70 (b)(3)(v)	• 1 TAC §354.1039(a)(4)(D) • UMCC	The Home Health DME and Supplies Exceptional

Federal Authority	State Authority	Description
	▸ Attachment B-2 ▸ Attachment B-2.2 ● STAR+PLUS Expansion, STAR+PLUS MRSA, STAR Health, and STAR Kids Contracts ▸ Attachment B-2 ● TMPPM, Durable Medical Equipment, Medical Supplies, and Nutritional Products Handbook, Section 2.2.3 "Home Health DME and Supplies Exceptional Circumstances Provision"	Circumstances provision is a requirement for MCOs to deliver home healthcare services in accordance with 42 CFR §440.70.

	Included in rate setting process?	Allowable cost/ expense?[i]	Offered to all plan members who meet eligibility criteria?	Set or approved by HHSC?
Services covered due to EPSDT	Yes	Yes	Yes	No
In-lieu-of services	Yes	Yes	No	Yes
Case-by-case services	No	No	No	No
Value-added services	No	No	Yes	Yes
Medically necessary CMS-covered outpatient drugs not yet on the Texas Medicaid formulary (pharmacy)	Yes	Yes	No	Yes
DME covered under the Home Health DME and Supplies Exceptional Circumstances provision	Yes	Yes	Yes	No

[i] Allowable cost: Chapter 6.1 of the UMCM: Allowable cost means a cost that is allocable to the Contract if: (a) the goods or services involved are specifically chargeable or assignable to the Contract in accordance with relative benefits received, (b) all activities which benefit from MCO's indirect cost will receive an appropriate allocation of indirect costs, (c) any cost allocable to the Contract under the principles provided for in this document may not be charged to other contracts to overcome deficiencies, to avoid restrictions imposed by law or terms of such contracts, or for other reasons.

Allowable expense: Attachment A of UMCC: Allowable Expenses means all expenses related to the Contract between HHSC and the MCO that are incurred during the Contract Period, are not reimbursable or recovered from another source, and that conform with the Uniform Managed Care Manual's "Cost Principles for Expenses."
Allowable costs/expenses govern what can be included in the calculation of net income. Value-added and case-by-case services are included in the Financial Statistical Report but on an informational basis only.

12/14/2020

Services Not Covered in the Texas Medicaid State Plan

Background:

As part of the implementation of Texas Government Code § 533.005(g), as adopted by Senate Bill (SB) 1177 (86th Legislature, Regular Session, 2019), HHSC is reminding Texas Medicaid MCOs of the processes available to cover services not included in the Texas Medicaid State Plan.

The below and attached guidance is intended to provide clarity on the definitions and operationalization of these types of services.

Key Details:

In some cases, Texas Medicaid MCOs cover services that are not included in the Medicaid State Plan. For example, Intensive Outpatient Programs (IOPs) and Partial Hospitalization Programs (PHPs) are not Medicaid State Plan services but may be covered under managed care through specific processes.

Allowable coverage of services not included in the Texas Medicaid State Plan fall into specific categories:

- Services covered due to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)
- In-lieu-of services
- Case-by-case services
- Value-added services
- Medically necessary Centers for Medicare and Medicaid Services (CMS) covered outpatient drugs not yet on the Texas Medicaid formulary
- Durable medical equipment (DME) covered under the Home Health DME and Supplies Exceptional Circumstances provision

See the attached guidance for more information about these coverage categories.

Additional Information:

Further, as part of the implementation of SB 1177, HHSC is evaluating additional evidence-based behavioral health services for cost-effectiveness to be offered in-lieu-of existing state plan services when medically appropriate. Texas Medicaid anticipates that 2021 managed care contracts will reflect updated in-lieu-of service offerings.

Resources:

Services Not Covered Under Texas Medicaid State Plan (Attached)

Contact:

Managed_Care_Initiatives@hhsc.state.tx.us

Attachment:

Services Not Covered Under Texas Medicaid State Plan.pdf

Type: Informational

To: MMP; STAR; STAR+PLUS; STARHEALTH; STAR_KIDS

From: Policy