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I. Pharmacy Services Introduction

A. Mission Statement

The Utah Medicaid Fee for Service (FFS) Pharmacy Program's mission is to develop and manage comprehensive pharmacy benefits and prior authorization services to ensure appropriate quality and utilization for Medicaid members.

B. Purpose

The information in this manual represents available services and policies that are designed to be used in conjunction with federal regulations and sections of the Utah Administrative Code R414-60 Medicaid Policy for Pharmacy Program.

Providers must be familiar with all current Utah Administrative Code Rules and federal regulations governing the Utah Medicaid FFS Pharmacy Program.

II. Pharmacy General Policy

This manual is updated quarterly and changes are announced through the Medicaid Information Bulletins (MIBs) published on the Medicaid Website. To sign up for the Utah Medicaid Newsletter and receive email notifications of policy changes and MIBs, refer to Medicaid Information Bulletins.

A. Mandatory Patient Counseling

For information regarding mandatory patient counseling, refer to R414-60-8.

B. Mandatory Generic

Utah Code 58-17b-606 mandates that when a multisource legend drug is available in the generic form, Utah Medicaid may only reimburse for the generic form of the drug except for drugs designated as "Brand required over generic". For additional information regarding the mandatory generic drug policy, refer to R414-60-4.

C. Drug Shortages

Utah Medicaid may consult the Food and Drug Administration (FDA) Drug Shortages database and the American Society of Health-System Pharmacists (ASHP) Drug Shortages List when making coverage determinations on non-preferred products. If a drug is not listed as being unavailable, the onus is on the pharmacy to demonstrate to Medicaid that a product is unavailable by providing one of the following:

- an invoice from a wholesaler that shows that the product is unavailable in the marketplace along with a brief description (e.g. discontinued, on backorder with expected availability date, etc.). In the case that a wholesaler does not have a product, but the product is available in the marketplace, the expectation is that a different provider would be capable of providing the product; or
- an official written communication from a manufacturer or a wholesaler indicating that a product has been discontinued, is currently on shortage (with expected date of availability), or another statement that there are no commercially available preparations.

Note: Member preference does not constitute a medical necessity.

D. Federal Medicaid Drug Rebate Program

Utah Medicaid only covers prescription medications that are eligible to be paid for with Federal funds. For prescription medications to be eligible for coverage using Federal Medicaid funds, drug manufacturers must participate in the Federal Medicaid Drug Rebate Program per federal law (42 USC 1396r-8).

Note: Certain medications are exempt from the Federal Medicaid drug rebate requirement by law (e.g. vaccines).

For additional information, refer to the Medicaid Drug Rebate Program

E. Prescription Order

All claims for covered medications, including over-the-counter medications, must be prescribed by a licensed prescriber acting within the scope of his or her licenses. Prescription orders must contain all the required information and be issued in compliance with all state and federal laws and regulations.

1. Pharmacist Prescribing

Effective January 1, 2022, a pharmacist may prescribe a prescription drug or device for specific conditions without the oversight of a physician. These conditions are determined to be public health concerns by the Department of Health in accordance with Utah Code § 358-17b-102. These conditions include, but are not limited to:

1. Post-exposure HIV prophylaxis;
2. Pre-exposure HIV prophylaxis;
3. Self-administered hormonal contraceptives
4. Smoking cessation; and
5. Naloxone

Effective January 1, 2022, Utah Medicaid will pay a dispensing fee for any prescriptions dispensed with a Medicaid-registered pharmacist's individual NPI. Pharmacists who wish to prescribe for Medicaid members will find more information on how to become a Medicaid provider here: https://medicaid.utah.gov/become-medicaid-provider/

F. Copay Policy

When applicable, Medicaid members are required to pay a co-payment for each prescription filled as described in 42 CFR 447.56(a)(1) and Utah State Plan, Attachment 4.18-C, Page 1 under "Pharmacy services", with a maximum of five (5) copays per month. Medicaid members enrolled in a Managed Care Entity (MCE) have some drugs that are covered under Fee-for-Service (FFS) Medicaid. Refer to section 4. Managed Care Entity Carve-Out

Pharmacy copays for Medicaid members enrolled in an MCE will be split between FFS Medicaid and the MCE plan:

- For drugs covered by the MCE, the maximum number of copays is three (3) per month.
- For drugs covered by FFS Medicaid, the maximum number of copays is two (2) per month.

Reversal of a previously filled prescription with a co-pay will require a refund of the co-pay to the Medicaid member and will cause the next prescription filled for that Medicaid member to be adjudicated with a co-pay.

Some Medicaid members or medications are exempt from the copayment requirement as described in Utah State Plan, Attachment 4.18-C, Page 3 under sub-bullet K.

Per federal regulation (42 CFR 447.52), a Medicaid provider may not refuse service to a Medicaid member based on their patient's inability to pay their copayment.

For additional information regarding copayment, refer to R414-60-6.

G. Preferred Drug List

1. Non-Psychotropic Medications

The Pharmacy and Therapeutics (P&T) Committee advises the DUR Board and DMHF in choosing preferred agent(s) for each selected class of drugs based on safety and clinical efficacy.

For additional information about the P&T Committee, meeting agendas, or meeting materials refer to Utah Medicaid P&T Committee or R414-60B.

2. Psychotropic Medications

For the purposes of the Preferred Drug List (PDL), psychotropic medications are defined as the following:

- Atypical antipsychotics,
- Antidepressants,
- Anticonvulsant/mood stabilizers,
- Anti-anxiety medications,
- Epilepsy medications, and
- Attention deficit hyperactivity disorder stimulants

If a prescriber writes "dispense as written" on a prescription for a non-preferred psychotropic drug, the pharmacy may submit a "Dispense as Written" (DAW) Code of "1" on the claim. Submitting the DAW code will allow the claim to bypass the prior authorization requirement for the non-preferred psychotropic drug at the point of sale. Checked boxes or pre-printed forms that include "dispense as written" are not acceptable substitutes for the prescriber writing, "dispense as written" on the prescription.

Note: The DAW Code will not allow claims for the brand-name version of multisource drugs to process, even though the brand-name version of the drug is listed as non-preferred and the prescriber writes "dispense as written" on the prescription. If a Medicaid member needs the brand-name version that is listed as non-preferred, a prior authorization request must be submitted to Utah Medicaid using the Medication Coverage Exception Request prior authorization form.

For more information, refer to R414-60B and the Preferred Drug List.

H. Days' Supply Policies

1. Maximum Days' Supply

Utah Medicaid will pay for up to a one (1) month supply of a medication per dispensing unless it is listed on the three-month supply list, located on the Preferred Drug List.

Medicaid requires a three-month supply for medications on the three-month supply list following a two-month window for dose titration and stabilization. When a member presents with a new prescription or a refill of a maintenance medication, the point of sale system will look back 75 days to identify two (2) consecutive fills of the same medicine at the same dose, indicating a stable maintenance dose has been achieved. If found, the claim will be rejected if billed for less than a three-month supply. Once a three-month supply of a medication has been filled, all subsequent fills of the same medicine at the same dose will fill for three months, assuming sufficient refills of the prescription remain.

For a three-month supply, Utah Medicaid fee for service members who are subject to cost-sharing will pay a single co-pay. Additionally, pharmacies will receive a single dispensing fee on prescriptions filled for a three-month supply.

Pharmacy staff are encouraged to work with prescribers to make any necessary changes to prescriptions to conform to this requirement. For example, when a pharmacy receives a prescription written for a 30-day supply with refills for a drug on this program, the pharmacy may contact the prescriber and recommend a modification to the original prescription for a three-month supply with refills, as appropriate.

The mandatory three-month policy does not apply to Indian Health Service providers, or Medicaid members receiving long-term services and support in nursing facilities, intermediate care facilities, or home and community-based waiver programs based on the members' certain

categories of aid. While not mandatory, three-month supply fills will remain optional for these groups.

If an exception to the Mandatory Three-Month Supply fill is needed for a patient not otherwise excluded from the requirement, a prescriber may submit the "Exception to Three-Month Supply" prior authorization form.

2. Insulin Pens

In 2019 the FDA requested the new wording "dispense in original sealed carton" on boxes of insulin pens for safety reasons. Therefore, breaking up boxes is no longer recommended.

Effective April 1, 2021, pharmacy point of sale claims for insulin pens may be billed for up to a 140-day supply, with a limit of one box for claims over 30-days, in accordance with the FDA's recommendation. Day supply on submitted claims should reflect the actual days the medication will last and/or expire.

www.fda.gov/drugs/drug-safety-and-availability/fda-advises-health-care-professionals-andpatients-about-insulin-pen-packaging-and-dispensing

3. Coverage of Early Fills of Medication

Effective November 1, 2021, Utah Medicaid has updated the Pharmacy Early Refill Policy to further improve member care. The early refill override request is now evaluated by the Pharmacy Team against medical necessity, as defined in Utah Medicaid Provider Manual General Information, Section 1, 8-1. An override is granted for early refill requests that rejects at the Pharmacy POS for Reject code 79, CC 1088 Refill Too Soon, if it is deemed medically necessary and in accordance with policy.

4.) Refill Tolerance

Utah Medicaid will pay for a prescription refill only when 80% of the previous prescription has been exhausted, except for opioid analgesics and controlled substances. The calculation is based on the most recent script fill date and quantity. Refills requested before the 80% of the day's supply that has been utilized will be rejected at the pharmacy point-of-sale. For example, a prescription for a 30 days' supply has been 80% exhausted on the 24th day after it was dispensed and can be refilled on the 25th day.

Effective April 1, 2020, Utah Medicaid established a refill tolerance of 85% for all controlled substances, including opioids. MME limits will still apply to opioid prescriptions.

Prescription refills must be requested by the Medicaid member, or the member's agent, based on continued medical necessity. Automatically refilled prescriptions, cycle-filled prescriptions, or medication synchronization, are not eligible for reimbursement.

5. Quantity Limits

Quantity limits are based on generally accepted pharmaceutical guidelines, FDA-approved labeling, efficient dosing regimens, and dosing recommendations. Refer to the Preferred Drug List for quantity limits which include opioid medications.

a) Short-acting and Long-acting opioid limit exceptions

Utah Medicaid restricts short-acting opioid quantity limits to 7 days or less for children 18 years of age and younger and in pregnant women. If a claim for a short-acting opioid is submitted through the point of sale system for a patient 18 years and younger, the

system will reject that claim. These days' supply limit can be overridden when a valid "cancer pain diagnosis code" is placed on the claim. For all opioid claims billed for an 8-day supply or greater, a reject message will display to the pharmacy that states, "Opioid claims for > 7-day supply for children 18 and younger require a prior authorization." This edit will be in addition to all existing opioid quantity limits and days' supply limitations.

New claims for long-acting opioids will require at least a 7-day trial of a short-acting opioid before long-acting opioid use. When a long-acting opioid prescription is submitted, the claims adjudication system will look back 45 days to identify a short-acting opioid. If a short-acting opioid claim is not identified, the claim for the long-acting opioid will be rejected.

Cumulative limits on opioid analgesics are waived for the current treatment of cancer-related pain. Claims for opioids for the treatment of cancer-related pain must be submitted with a current valid ICD-10 diagnosis code G89.3 Neoplasm-related pain (acute) (chronic) to bypass the quantity, MME, or MED limits listed in the Resource Library.

The prescriber is responsible to provide the current correct diagnosis for narcotic analgesics for cancer pain.

The diagnosis code may be hand-written by the prescriber on the prescription or computer generated by prescribing software. Pharmacy providers may also obtain diagnosis codes verbally from prescribers, and **Note:** the date, time, and name of the physician's representative providing the diagnosis code on the original hard-copy prescription. In addition, updated or renewed prescriptions for a given drug may reference an original handwritten or computer-generated prescription for the appropriate diagnosis code.

The pharmacist must enter the diagnosis code into the appropriate diagnoses field when processing a claim.

Note: If a pharmacy fills a narcotic analgesic prescription that does not comply with the requirements above, funds paid by Medicaid will be recovered through post-payment review.

b) Antipsychotic Injections

Effective August 1, 2020, antipsychotic injections are restricted to members 18 years of age and older. For more information, refer to the Medicaid Information Bulletins or Preferred Drug List.

III. Member Eligibility

For information regarding verification of a member's Medicaid eligibility, refer to R414-60-3, or the Eligibility Lookup Tool.

Medicaid members may be referred to and enrolled in the Restriction Program. For more information, contact us at 801-538- 9045 or toll-free at 1-800-662-9651 #900.

A. Dual Eligible Members (Medicare & Medicaid)

For information regarding dual eligible members on Medicare Part D, refer to R414-60-3.

Medicaid may cover any remaining patient liability for Medicare Part B covered drugs for dual-eligible members as described in Utah State Plan, Attachment 4.19-B, Supplement 1 to Attachment 4.19-B, Page 3.

For billing Medicare/Medicaid crossover claims, see Section I: General Information in Utah Provider Manual, 11-5.1 Medicare Crossover for more information.

IV. Pharmacy Program Coverage

A. Covered Services

1. Medical Billing for Prescription Medications Using HCPCS or CPT Codes

Pharmacy-related HCPCS and CPT code coverage can be found using the Coverage and Reimbursement Code Lookup. Providers shall review the HCPCS NDC Crosswalk using the Fee Schedule Download Tool to ensure the NDC being used is also covered. For additional information contact the Utah Medicaid Pharmacy Team at 801-538-6155 option 3, 3, 2.

2. Compounded Prescriptions

Covered compounds may contain both covered and non-covered ingredients; however, if a compound contains non-covered ingredients then it must be submitted with the Submission Clarification Code = 8.

The Utah Medicaid Fee for Service pharmacy program has identified pharmacy compound claim submission errors. We encourage all providers billing compound claims to submit the claim properly. For additional assistance with processing pharmacy claims please refer to the Utah Medicaid Pharmacy Compound Billing Alert Fax Blast here https://medicaid.utah.gov/pharmacy/resource-library/ or contact the Utah Medicaid Pharmacy Team at 801-538-6155 option 3, 3, 2.

Note: Dispensing fee does include the preparation costs for compounded prescriptions. A pharmacy may not charge a Medicaid member an additional fee for any service that is reimbursed as part of the dispensing fee. 3. Diabetic Testing Supplies

a) Continuous Glucose Monitors (CGM)

Preferred glucose monitors are based on the preferred test strips being available on the Preferred Drug List for Medicaid members at no charge. Claims for these preferred glucose monitors can be submitted using the billing information that is included on the Preferred Drug List (PDL) under Diagnostic Products.

Effective April 1, 2021, Utah Medicaid covers CGM through the pharmacy point of sale system. The Dexcom G6 CGM system will be the preferred product and Freestyle Libre and Guardian Connect systems will be non-preferred. The Utah Medicaid PDL can be found here https://medicaid.utah.gov/pharmacy/preferred-drug-list/. A clinical prior authorization will be required for coverage for all CGMs and can be found here https://medicaid.utah.gov/pharmacy/prior-authorization/.

Coverage of CGM CPT Codes can be found in the Coverage and Reimbursement Code Lookup here https://health.utah.gov/stplan/lookup/CoverageLookup.php b) Diabetic Testing Strips and Lancets

Preferred blood glucose test strips on the Preferred Drug List are a Medicaid-covered benefit through the pharmacy program, up to a maximum of 200 strips per month. Prescriptions for quantities over 200 test strips require prior authorization using the Medication Coverage Exception Request prior authorization form.

Claims for non-preferred diabetic supplies must be submitted through the medical supply program as Durable Medical Equipment (DME) and will not be authorized through the pharmacy point-of-sale system.

4. Managed Care Entity Carve-Out

The following classes of medications and individual drugs are carved out from ACO coverage and are part of the FFS Medicaid benefit:

- Transplant Immunosuppressive Drugs
- Attention Deficit Hyperactivity Disorder (ADHD) Stimulant Drugs
- Antipsychotic Drugs
- Antidepressant Drugs
- Anti-anxiety Drugs
- Anticonvulsant Drugs
- Hemophilia Drugs
- Opioid Use Disorder Treatments

5. Tobacco Cessation Products

Both over-the-counter and prescription tobacco cessation products are available under the pharmacy program for Medicaid members with a prescription. The prescriber can provide a prescription to be filled by the pharmacy for the member to be covered by Medicaid. For additional information, refer to Utah Medicaid Tobacco Cessation Program.

6. Cough & Cold Products

Under R414-60-5, Medicaid covers prescription cough and cold preparations meeting the definition of a covered outpatient drug.

7. Opioids

b) Morphine milligram equivalents (MME) & cumulative morphine equivalent dosing (MED)

Utah Medicaid uses MME and cumulative daily MED methodology when adjudicating all opioid claims for the treatment of non-cancer pain.

- January 1, 2019: the pharmacy claims adjudication system began using two sets of MED thresholds, depending on a member's opioid claim history in the last 90 days
  - 90 MED limit is applied to prescriptions for members who have not had a claim for an opioid in the last 90 days from the index opioid prescription
  - 180 MED limit is applied to prescriptions for members who have had a claim for an opioid in the last 90 days from the index opioid prescription.
- July 1, 2019, the 180 MED threshold was reduced to 150 MED
- January 1, 2020, the 150 MED threshold was reduced to 120 MED
- July 1, 2020, the 120 MED threshold was reduced to 90 MED

c) Non-opioid alternatives

Utah Medicaid recommends non-opioid analgesics, antidepressants, and anti-seizure medications for the treatment of some forms of chronic pain. The PDL has a variety of FDA-approved, CDC recommended, non-opioid treatment options for pain available for Utah Medicaid members, and many are available as a three-month supply. Refer to the Preferred Drug List for covered non-opioid options.

d) Initial fills of short-acting opioids

Utah Medicaid restricts the initial fill of short-acting opioids that exceed a 7-day supply or 3 days for dental providers. When a claim for a short-acting opioid is submitted to Utah Medicaid, the pharmacy claims processing system will determine whether the member has had a prescription for the same medication in the previous 60 days. If the member has not had a claim for the same medication in the previous 60 days, the system will treat the claim as an initial fill and allow no more than a 7-day supply. If a claim has been filled for the member for the same medication in the previous 60 days, then the claims processing system will allow the claim to process for up to a 30-day supply; however, the claim will be subject to all limitations and restrictions.

(1) MME limit: Initial fills for opioid naïve members

Effective August 1, 2021, the following edits will be applied:

- Soft messaging educational campaign stating "A max limit of 50 MME for opioid naïve members is recommended by the CDC"
- Immediate release, the short-acting opioid formulation must be filled before a long acting opioid
- Day supply limitations - 3 days' supply for dental providers and 7 days for all other providers
- Individual opioid quantity limits

8. Biologic medications and substitutions of biosimilars

A biosimilar is a biologic product that is highly similar to the U.S. Food & Drug Administration (FDA) approved biologic, known as reference product or parent product. To be FDA-approved as a biosimilar, the product must have the following: same mechanism of action, dosage form, strength, and route of administration as the reference product. Also, a biosimilar must have no clinically meaningful differences in terms of safety, purity, and potency when compared to the parent product.

Additional requirements must be met for a biologic to be titled as an interchangeable biosimilar. These requirements include not only showing that the product is expected to produce the same clinical result as the reference product in any given patient, but also that switching back and forth between the parent biologic product and the biosimilar causes the patient no additional risks in terms of safety or diminished efficacy as using only the reference product.

The key difference between a biosimilar and an interchangeable biosimilar is that the interchangeable biosimilar can be substituted for the reference product by the dispensing pharmacist without prescriber involvement.

The FDA publishes the "Purple Book" (https://www.fda.gov/drugs/therapeutic-biologicsapplications-bla/purple-book-lists-licensed-biological-products-reference-product-

exclusivityand-biosimilarity-or) that lists FDA-approved biological products, which includes biosimilars and interchangeable biosimilars. This publication serves as a reference to healthcare providers to determine which biological products are FDA-approved as reference products, biosimilars, or interchangeable biosimilars.

Utah Medicaid will continue to use the FDA "Purple Book" as a reference and unless otherwise limited through the prior authorization process, the State will not mandate interchange of biosimilars unless they are listed as interchangeable.

Utah Medicaid evaluates reference products and biosimilars for safety and efficacy and may "prefer" one or more over others. When a prior authorization is received for a "non-preferred" reference product or biosimilar the Medicaid staff will contact the requesting provider to ask that they switch to the "preferred" version. As per above, the State will not mandate interchange/substitution of biosimilars unless they are listed as interchangeable.

9. Outpatient cancer therapy

For information about outpatient cancer therapy, refer to R414-60-7.

B. Non-covered services

For information on non-covered services and limitations that apply to all Utah Medicaid programs and the circumstances in which a Medicaid member may be billed for non-covered Medicaid services, refer to R414-60-5.

V. Pharmacy Prior Authorization

A. Prior Authorizations

Pharmacy prior authorizations must be initiated by a Medicaid prescriber. Forms and criteria information can be found on the Utah Medicaid Pharmacy web page, Prior Authorization.

For prescriptions covered by the member's ACO, contact the ACO for their PA procedures. Refer to the Resource Library for updated ACO billing information.

Per R414-60-5, a pharmacy provider may dispense up to a 72-hour supply of the medication without obtaining prior authorization when a medical emergency occurs. The pharmacist should use professional judgment to define a medical emergency. All subsequent claims must satisfy all prior authorization criteria or other limitations for the medications.

The pharmacy must submit prior authorization type code (461-EU)=2 and prior authorization number submitted (462-EV)=72.

The 72-hour override is limited to two per month per NDC per member. All copay and dispensing fee rules apply.

For additional information regarding pharmacy prior authorizations, refer to R414-60.

B. Pharmacy Continuation of Care

Members transitioning to Medicaid from other payers may encounter differences in pharmacy coverage (preferred/non-preferred status) resulting in claim denial. The non-preferred policy requires that the member try and fail at least one preferred agent, however, exceptions may be made when a request is received for a continuation of care.

Continuation of care (COC) is defined as evidence of the member being on the requested medication for a minimum of 60 out of the last 90 days unless the medication is used emergently. Evidence, or supporting documentation, to request support of approval must be submitted with the Medical Exception Prior Authorization Request and may include any of the following:

- Chart notes
- Fill history obtained from the controlled substance database or dispensing pharmacy claims history
- E-mail messages provided by prescriber's clinical staff
- Letter of medical justification
- Medicaid claims history
- Verbal or written attestation of medical need provider by prescriber's clinical staff

If sufficient documentation does not exist, the request will be evaluated against the clinical judgment and a limited transitional fill may be approved. In this instance, adequate documentation may be required for additional approvals. Information on the continuation of care policy can be found in the Medicaid Pharmacy Manual here https://medicaid.utah.gov/utah-medicaid-officialpublications/?p=Medicaid%20Provider%20Manuals/Pharmacy/.

C. ADHD Stimulants

Utah Medicaid policy supports the safe and appropriate use of ADHD stimulant medications. This policy is developed in alignment with the American Academy of Pediatrics and the University of South Florida clinical guidelines.

Effective July 2020, age edit limitations apply when a claim for an ADHD stimulant is processed through the pharmacy point of sale:

- ADHD stimulant prescriptions for children under 4 years of age.
- ADHD stimulant prescriptions for Adzenys ER suspension (susp.), Dyanavel XR, Desoxyn, Adhansia XR, Jornay PM, and Cotempla XR Orally Disintegrating Tablet (ODT) for children under 6 years of age.

Also, effective April 2021, a multiple agent edit and a cross-class edit limitation will apply when claims for ADHD stimulants are processed through the pharmacy point of sale:

- Three or more unique ADHD stimulant medications were prescribed concurrently for at least 30 days in the last 45 days.
- Cross-class prescribing of ADHD stimulant medications from the amphetamine class and the methylphenidate class for at least 30 days in the last 45 days for children under 18 years of age.

Effective January 1, 2022, a peer to peer educational intervention was implemented to prescribers of high dose stimulant medications. This educational intervention emphasizes prescribing within FDA approved labeling and potential risks of high dose prescribing.

Exceptions to ADHD stimulant safety edits are reviewed on a case by case basis by submitting the ADHD Stimulants Prior Authorization Form.

D. Rare Disease

The "Rare Disease Medications" prior authorization form will be required for approval of medications that treat a rare disease and for which prior authorization is required but there is not a drug-specific form available. In determining which drugs will require the "Rare Disease Medications" PA form, the Department will include (but not be limited to) consideration of the drug's FDA approval status:

- "orphan status designation" approval: drugs and biologics intended for the safe and effective treatment, diagnosis, or prevention of rare disorders that affect fewer than 200,000 people in the U.S.
- "rare pediatric disease" approval: "the orphan [drug population] subset must be serious or life-threatening and the serious or life-threatening manifestations of the orphan subset must primarily affect individuals aged from birth to 18 years."

Effective September 1, 2020, Rare Disease Medications Prior Authorization is required for any medications that have orphan drug designation as mentioned above and may be required for other, non-orphan medications for rare diseases.

E. New Drug Products

Any new drug product(s) will require a prescriber to submit a New to Market Drugs prior authorization request to Utah Medicaid. For additional information regarding new drug products, refer to R414-60-9

F. Off-label Use

Utah Medicaid may restrict coverage of a drug to the FDA-approved indication (labeled indication) or compendia per federal law 42 U.S.C. 1396r-8(k)(6). Prescribers may request prior authorization by submitting the Medication Coverage Exception Request.

VI. Drug Utilization Review Board (DURB) Program

The purpose of the Utah Medicaid DUR program is to promote the evidence-based best clinical practice as well as to identify patterns of fraud, abuse, gross overuse, and inappropriate or suboptimal treatment. We aim to partner with prescribers, pharmacists, and Medicaid patients to enhance prescribing and dispensing practices as well as medication use by individual patients. Pharmacy staff utilizes communication tools, such as motivational interviewing, to promote and reinforce best practices in the delivery and administration of pharmacy benefits.

A. Prospective DUR

Prospective drug utilization review involves a review of drug therapy before each prescription is filled or delivered to a member and includes counseling of the member or their caregiver. This counseling is based on evidence-based predetermined clinical standards.

1. Attention Deficit Hyperactivity Disorder (ADHD) Stimulants

Stimulants medications are utilized first-line to treat ADHD. These agents have high misuse potential and are associated with significant, lasting adverse effects when taken at chronically high doses. Point-of-sale edits and prior authorization requirements have been implemented based on guideline recommendations to minimize concurrent use of different classes of stimulant medication and prevent utilization of unsafe chronic stimulant doses.

2. Benzodiazepine and Opioid Concurrent Use

Utah Medicaid has begun a multi-stage effort to identify and limit the concurrent filling of benzodiazepine and opioid medications. This initiative supports CDC safety guidance that recommends against combined use, which is associated with the risk of fatal overdose. Currently, an automated process monitors and reports when an individual is co-prescribed opioids and benzodiazepines. The peer to peer team conducts outreach to identified prescribers to alert them of patients receiving concurrent therapy, provide education around concurrent use avoidance, and encourage prescription drug monitoring program (PDMP) use before

prescribing a Schedule II controlled substance, per the Federal HR6, SUPPORT for Patients and Communities Act.

Combined use of opioids and benzodiazepines potentiate respiratory depression, which may result in nonfatal overdose and death. Utah Medicaid supports FDA labeling and CDC best practice and safety standards which advise against concurrent use. (https://www.cdc.gov/drugoverdose/prescribing/guideline.html)

- July 1, 2019: Concurrent prescribing of long-acting opioid medications and benzodiazepines are restricted through the pharmacy point of sale system. When a claim for either a long acting opioid or a benzodiazepine is submitted, the system will look back 45 days to find any paid claims for either benzodiazepines or long-acting opioids. If a paid claim for a benzodiazepine is found, the long-acting opioid claim will be rejected. Likewise, if a paid claim for a long-acting opioid is found, the benzodiazepine claim will be rejected. Any exceptions to this concurrent use restriction will be evaluated through the prior authorization process, using the Opioids Prior Authorization Form, found on the Utah Medicaid Pharmacy Website here.
- October 1, 2019: Utah Medicaid deployed a Drug Utilization Review (DUR) hard edit when a short-acting opioid claim is filled concurrently with a benzodiazepine. The DUR hard edit will require pharmacist input of an NCPDP override code, documenting the intervention made, before the claim will process. All other existing opioid edits will apply to the processing of opioid claims.

Utah Medicaid encourages filling pharmacists to incorporate these standards when filling opioid–benzodiazepine prescriptions:

- Routinely check the controlled substance database with the filling of each opioid prescription
- Proactively counsel patients about the risks of respiratory depression when combined use is identified
- Proactively offer naloxone and educate on the appropriate use
- Proactively outreach to prescribers to consider other, safer combinations

3. Opioid Use in Pregnancy

In March 2016, the FDA strengthened warnings about the risks related to opioid use and potential misuse, abuse, and addiction. One of those risks is Neonatal Abstinence Syndrome (NAS) or Neonatal Opioid Withdrawal Syndrome (NOWS) which may occur in infants who are chronically exposed to opioids in utero.

NAS/NOWS is a withdrawal syndrome that occurs in infants who were exposed to opioids in utero. The syndrome is characterized by tremors, irritability, poor feeding, respiratory distress, and seizures, all of which develop shortly after birth. From 2004 to 2014, the incidence of NAS in the United States increased from 1.5 to 8.0 per 1,000 hospital births, a more than fivefold increase. Carefully consider any use of opioids in the management of pregnant individuals. This policy does not apply to pregnant women on methadone maintenance for the treatment of opioid use disorder.

- October 1, 2019: Utah Medicaid restricts opioid quantity limits to 7 days or less for pregnant individuals.

- If a claim for an opioid is submitted through the point of sale system for more than a 7-day supply for a pregnant individual, the system will reject that claim.

4. Medication-Assisted Treatment (MAT) for Opioid Use Disorder

The Utah Medicaid PDL includes medications used for the treatment of opioid use disorder. Refer to the Preferred Drug List for coverage options.

Effective January 1, 2021, Utah Medicaid will limit the use of opioid medications in members who are also receiving medications to treat opioid use disorder (MAT). When a claim for an opioid medication is processed through the pharmacy point of sale system, the system will look back to identify if a claim for medication-assisted treatment (MAT) has been processed in the last 45 days. If the system recognizes that a claim for MAT has been processed in the last 45 days, the system will limit the opioid to a supply of 7 days or less, regardless of the prescribed quantity/duration. If the system does not identify a concurrent claim for MAT in the last 45 days, then the opioid will process without a 7-day limitation. All opioid policy limits still apply.

5. Gabapentin/Pregabalin Concurrent Use

The Drug Utilization Review Board reviewed the safety and misuse/abuse potential of gabapentin and pregabalin during the January 2020 meeting. To promote best practice and safety standards that align with the Food and Drug Administration (FDA) labeling, Utah Medicaid set prospective drug utilization review quantity limits for gabapentin at 3,600 mg/day and pregabalin at 600 mg/day effective April 1, 2020. In addition, concurrent use of gabapentin and pregabalin will not be permitted. Claims processed through the point of sale system that exceeds established quantity limits or use standards will require prior authorization.

B. Retrospective DUR

Retrospective drug utilization interventions involve a review of claims data or other historic records to inform policy and create interventions to improve patient outcomes. Outcome measures are derived from CMS guidance and measures outlined by the National Committee for Quality Assurance (NCQA).

1. Hemophilia Medication Management

Fee-for-service members and their families receive comprehensive care management services provided by a multidisciplinary team of healthcare professionals from the Hemophilia Treatment Centers and the Utah Medicaid Pharmacy Team, per national treatment guidelines. Care management includes but is not limited to: claims review, verification of monthly eligibility and ongoing enrollment requirements, contact with eligible FFS Medicaid members to assess their hemophilia needs and well-being, continuous outreach to ensure adherence and transparency of care, and coordinating with in-home nursing and the Hemophilia Treatment Centers as necessary. Members of the care team from the Utah Medicaid Pharmacy include clinical pharmacists and pharmacy technicians that received comprehensive training from the Hemophilia Treatment Centers, as well as online training.

2. Hepatitis C Medication Adherence

Adherence to Hepatitis C antiviral medication therapy is essential for ensuring a treatment cure for undetectable viral loads. Pharmacy staff telephonically reach out to patients who have been non-adherent to their Hepatitis C medications during a course of therapy and provider support and identify barriers to adherence. Follow-up is conducted to promote medication adherence for the remainder of antiviral treatment.

For information about the Drug Utilization Review (DUR) Board, meeting agendas, or meeting materials, refer to the Utah Administrative Code, R414-60A, and Utah Medicaid Drug Utilization Review Board.

3. Antipsychotics in Children

Utah Medicaid implemented a new policy on October 1, 2019, to monitor and manage antipsychotic (AP) medications prescribed to members 19 years of age and younger.

Retrospective Drug Utilization Review (DUR) peer to peer educational interventions that support the American Academy of Child and Adolescent Psychiatry best practices for use of AP in children addresses the following:

- Use of other first-line services (psychosocial counseling and safer medications) before initiation of AP
- Dosing of AP should follow the "start low and go slow" approach
- Identification of "higher than recommended" doses for AP
- Careful and frequent monitoring of AP-related side effects ○ Metabolic screening ○ Body Mass Index, weight gain ○ Assessments for movement disorders
- Use of AP in very young children (e.g. younger than 6 years old)
- Use of multiple concurrent AP

Utah Medicaid requires a diagnosis code on all prescription claims for AP medications. Prescribers must include the diagnosis codes with each prescription for an AP given to a child 19 years of age and younger. Pharmacies are required to enter the diagnosis code into the point of sale system when processing a claim for an AP. Retrospective peer-to-peer outreach will address off-label use of AP in this vulnerable population.

High dose limits for AP will be established in the pharmacy point of sale system. Very high doses of AP have not been proven effective in children and may be associated with a greater incidence of adverse effects, including movement disorders. Claims for AP submitted to Utah Medicaid that exceeds the pre-established limits will be rejected at the pharmacy point of sale and require prior authorization.

Effective April 1, 2020, Utah Medicaid requires documentation of AP-related side effects, monitoring, and management, for all PA requests for AP in members 19 years of age and younger to align with the American Academy of Child and Adolescent Psychiatry best practices. PA requests that do not include documentation of AP-related side effects, monitoring, and management, as mentioned above, will be denied.

For additional information, refer to R414-60-5.

a) Monitoring of Antipsychotic-related side effects required when treating children

Children enrolled in Medicaid receive antipsychotic medications at a substantially higher rate than non-Medicaid pediatric populations.1 Antipsychotic use in children is frequently "off label" and prescribed before safer, first-line options have been trialed.2 Antipsychotic medications can have severe side effects including metabolic changes, weight gain, and movement disorders. These side effects can be irreversible.3 Because of these risks, the "Antipsychotics in Children" prior authorization requires documentation of monitoring of antipsychotic-related side effects OR clinical rationale for the lack thereof.

The American Academy of Child and Adolescent Psychiatry endorse the American Diabetes Association and American Psychiatric Association recommendations that **children receiving antipsychotic medication** should have side effects monitored via parameters measured at treatment initiation and regularly repeated thereafter, including:

Parameter	Frequency of Monitoring
Personal and family history of obesity, diabetes, dyslipidemia, hypertension, or cardiovascular disease	Treatment initiation, annually
Weight	Treatment initiation; month1, 2, 3, and annually
Waist circumference	Treatment initiation, annually
Blood pressure	Treatment initiation, 3 months, annually
Fasting plasma glucose	Treatment initiation, 3 months, annually
Fasting lipid profile (HDL, LDL, TG, TC) *	Treatment initiation, 3 months, then every 6 months

HDL: high-density lipoprotein
LDL: low-density lipoprotein
TG: triglyceride
TC: total cholesterol

Medicaid's "Antipsychotics in Children" prior authorization approval requires documentation of monitoring of antipsychotic-related side effects OR clinical rationale for the lack thereof with every request. Monitoring should include the following:

- Metabolic screening at baseline, 3 months, 9 months, and annually;
- Body Mass Index OR appropriate growth measurement; and
- Assessment for movement disorders using a standardized assessment tool

VII. Billing

Utah Medicaid requires all pharmacy claims to be submitted electronically through the pharmacy point-of-sale system using the National Council of Prescription Drug Plan (NCPDP) version D.0 standard. The point-of-sale system provides pharmacists with the capability to submit pharmacy claims electronically and have "real-time"

claim processing. To assist pharmacies in submitting electronic claims, Utah Medicaid posts an NCPDP version D.0 payer sheet located in the Resource Library.

Utah Medicaid reviews all pharmacy claims to identify inappropriately billed prescriptions. Medicaid will work with the pharmacy to correct erroneous claims within the timely filing. Repeat issues may be referred to OIG for further investigation per Utah Code Section 63A-13-3.

A. Procedure Codes

Outpatient pharmacy claims submitted to Utah Medicaid electronically using the NCPDP Version D.0 standard do not need to be submitted with a Current Procedural Terminology (CPT®) code or Healthcare Common Procedure Coding System (HCPCS) code.

B. Decimal quantities

Pharmacies must submit claims to Utah Medicaid using the actual metric decimal quantities of medications dispensed to Medicaid members based on the National Council of Prescription Drug Plans (NCPDP) billing unit for drugs.

Rounding units, packages, or sizes, or submitting quantities that are inconsistent with the NCPDP billing unit on a claim is not allowed and will be rejected at the point of sale.

C. National prescriber identifier

Federal regulation 42 C.F.R. 455.410(b) requires all prescriptions for Utah Medicaid members to be issued by a prescriber who is enrolled with Utah Medicaid. Prescriptions that are issued by a non-enrolled prescriber or claims submitted with a National Prescriber Identifier (NPI) not associated with an enrolled prescriber will be denied.

Utah Medicaid requires the NPI submitted on a pharmacy claim to be the NPI of the prescriber that issued the prescription. Claims submitted with an incorrect prescriber NPI will either be denied or subject to recoupment on post-payment review.

D. 340B billing

Covered entities participating in the 340B Program must comply with all 340B Program requirements https://www.hrsa.gov/opa/index.html. States shall collect Medicaid rebates for covered outpatient drugs, unless the drug was subject to a 340B Drug Discount Program discount (42 U.S.C. §1396r-8(j)(1)) and indicated as such per the state's policies. Medicaid excludes claims from drug rebate invoicing if the provider indicates on the claim that a 340B drug was dispensed.

340B Program compliance rests entirely on the covered entity. 340 B-covered entities can be sanctioned for causing duplicate discounts or drug diversion (42 U.S.C. § 256B).

Each 340 B-covered entity should carefully review its claims to ensure the indicators and actual acquisition costs were correctly billed. A covered entity identifying 340B claims that were billed inappropriately should resubmit claims to Medicaid to correct the 340B indicator(s) or correct the actual acquisition cost submitted within the timely filing.

If the covered entity is unable (due to timely filing or otherwise) or unwilling to submit a corrected claim, the 340B covered entity must work directly with the manufacturer to resolve the duplicate discount issue that resulted from its actions.

1. 340B Medical

All claims submitted to Utah Medicaid from a 340B covered entity for medications that were purchased through the 340B program must be submitted with the provider's 340B actual acquisition cost as the billed charges and the "UD" modifier after the HCPCS code on each claim line. Claims submitted without the provider's 340B actual acquisition cost as the billed charges and the "UD" modifier on the claim line indicate that the covered entity purchased the medication outside of the 340B program and Utah Medicaid will pursue the federal Medicaid drug rebate on those claims.

For dual-eligible beneficiaries who participate in both the Medicare and Medicaid programs, when a 340B covered entity submits a crossover drug claim to Utah Medicaid, it must contain a "JG" or "TB" modifier.

When applicable, providers are required to report either modifier "JG" or "TB" on OPPS claims (bill type 13X). Though modifier "TB" is an informational modifier, reporting is mandatory for the following providers:

Hospital Type (determined by CMS)	Pass-through Drug (SI "G")	Separately Payable Drug (SI "K")	Vaccine (SI "F" "L" or "M")	Packaged Drug (SI "N")
Not Paid under OPPS				
CAH	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Non-Excepted Off-Campus PBD	TB	TB	N/A	TB or JG, Optional

Paid under the OPPS, Excepted from the 340B Payment Adjustment for 2018				
Children's Hospital	TB	TB	N/A	TB or JG, Optional
PPS-Exempt Cancer Hospital	TB	TB	N/A	TB or JG, Optional

2. 340B Outpatient pharmacy (POS)

All claims submitted to Utah Medicaid from a 340B covered entity for medications that were purchased through the 340B program must be submitted with the provider's 340B actual acquisition cost in the Ingredient Cost Field, a value of "8" in the Basis of Cost field, and a value of "20" in the Submission Clarification Code field. Claims submitted without the provider's 340B actual acquisition cost in the Ingredient Cost Field, a value of "8" in the Basis of Cost field, and a value of "20" in the Submission Clarification Code field indicate that the covered entity purchased the medication outside of the 340B program and Utah Medicaid will pursue the federal Medicaid drug rebate and supplemental rebate on those claims.

Claims submitted to Utah Medicaid from a 340B covered entity for medications that were not purchased through the 340B program may be submitted in accordance with Utah Medicaid and the pharmacy's normal business practices.

340B covered entities may not utilize contract pharmacies to bill Utah Medicaid, unless the covered entity, the contract pharmacy and the State Medicaid agency have established a written arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the OPA (Office of Pharmacy Affairs), HRSA (Health Resources & Services Administration), by the 340B covered entity.

E. Provider administered drugs

The provider administered drugs are administered in physicians' offices or outpatient facilities by doctors or eligible staff. These drugs must be reasonable, necessary, and indicated for the diagnoses, or effective treatments of specific illnesses or injuries based on accepted standards of medical practice. All other program plan coverage and limitations still apply.

As described in Utah State Plan, Attachment 4.19-B on Page 19b under Provider Administered Drugs section, covered provider administered drugs will be reimbursed according to the Average Sale Price (ASP) Drug Pricing File, published quarterly by the Centers for Medicare and Medicaid Services (CMS), for drugs that have an ASP price set by CMS.

Covered provider administered drugs for which CMS does not publish an ASP price will be reimbursed in accordance with the Utah Medicaid fee schedule published on Medicaid's Coverage and Reimbursement Code Look-up Tool.

Coverage and payment rates for provider administered drugs are based on the Healthcare Common Procedure Coding System (HCPCS) code and HCPCS units. Coverage status and HCPCS code rates can be verified by using the Utah Medicaid, Bureau of Healthcare Policy and Authorization, Coverage and Reimbursement Code Lookup. Covered NDCs can be verified by using the Utah Medicaid, Coverage and Reimbursement Fee Schedule Download, HCPCS/NDC Crosswalk.

Additionally, claim lines for provider administered drugs must contain both the appropriate HCPCS codes and the National Drug Code (NDC) of the medication administered to the Medicaid member. The NDC of the product administered to the Medicaid member must be valid and eligible for the federal Medicaid drug rebate and active in order for the claim line to be considered for reimbursement. Utah Medicaid will compare the submitted HCPCS code to the submitted NDC by using a crosswalk, available at Bureau of Healthcare Policy and Authorization, Coverage and Reimbursement Fee Schedule Download, HCPCS/NDC Crosswalk.

If the submitted combination is unmatched, the claim will be denied. The HCPCS to NDC crosswalk and billing requirements apply to claims administered in physician offices (CMS-1500 claim) and in outpatient settings (UB-04 claim).

Providers and interested parties who wish to submit requests for consideration of additional HCPCS to NDC matches, or to make changes to existing matches, may do so via the Physician Administered Review Request Form.

Note: NDCs must be submitted with eleven (11) digits in a 5-4-2 digit format (without dashes). NDCs submitted as ten (10) digit codes or eleven (11) digit codes with dashes will result in the claim being denied. The first five (5) digits of the NDC are the manufacturer's labeler code, the middle four (4) digits are the product code, and the last two (2) digits are the package size. If one were to encounter a NDC that is less than eleven (11) digits, add the missing digits as follows:

- For a 4-4-2 NDC, add a 0 to the beginning of the code as the first digit.
- For a 5-3-2 NDC, add a 0 as the sixth digit.
- For a 5-4-1 NDC, add a 0 as the tenth digit

A covered entity using medications purchased through the 340B program should refer to the 340B chapters of this manual for additional information.

The following information must be provided on a CMS-1500 Claim Form when billing for provider administered drugs:

- NDC – Box 24D, shaded area
- Drug Unit Price – Box 24F, shaded area
- Basis of Measurement Qualifier and Units – Box 24G, shaded area. Use the following qualifiers: ML – for milliliters
- GR – for grams UN – for units
- F2 – for international units

When billing the CMS-1500 electronically, the information needs to be reported in the following X12 fields (contact your software vendor for specific information):

- 2410 LIN03= NDC number preceded with N4 (LIN02=N4)
- 2410 CTP05-1= Units qualifier (GR, ML, UN, F2)
- 2410 CTP04= Number of units (place the number of units immediately after the units qualifier)
- 2410 CTP03= Cost or Unit Price

Outpatient hospital claims that include lines for drugs must provide the NDC when billing Medicaid on the UB-04 claim form. The NDC code must be included on the claim line immediately below the REV Code and Procedure Code (Form locator 43), the Units preceded by a qualifier (Form locator 46), and the Unit Price (Form locator 47).

When billing the UB-04 electronically, the information needs to be reported in the following X12 fields (contact your software vendor for specific information):

- 2410 LIN03= NDC number preceded with N4 (LIN02=N4)
- 2410 CTP05-1= Units qualifier (GR, ML, ME, F2)
- 2410 CTP04= Number of units (place the number of units immediately after the units qualifier)
- 2410 CTP03= Cost or Unit Price

For provider administered drugs used for the treatment of an opioid use disorder, a pharmacy may bill Medicaid. The pharmacy may only release this provider administered drug used for the treatment of an opioid disorder to the administering provider or provider's staff for treatment

VIII. Reimbursement

A. Hemophilia Reimbursement

For information regarding hemophilia reimbursement, refer to the State Plan, Attachment 4.19B, Page 22g and R414-60-7.

B. Utah Maximum Allowable Cost and NADAC

Effective October 1, 2020, UMAC pricing for antihemophilia products have been implemented to maintain the UMAC rates. For information regarding the Utah Maximum Allowable Cost (MAC), refer to R414-60-7.

For questions or concerns regarding NADAC pricing, contact Myer's National Average Drug Acquisition Cost (NADAC) Help Desk at (855) 457-5264 or info@mslcrps.com.

Pharmacies may also submit NADAC pricing inquiries using the following form:
https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/hdform.pdf

C. Drug Pricing Metrics

Utah Medicaid reimburses pharmacies for prescription drugs in accordance with the Utah State Plan ATTACHMENT 4.19-B. Published pricing metrics used for reimbursement logic include Wholesale Acquisition Cost (WAC), Federal Upper Limit (FUL), National Average Drug Acquisition Cost (NADAC), and Utah Maximum Allowable Cost (UMAC). Pharmacy submitted pricing that is included in the pricing logic includes the amount billed, the usual and customary charge billed to the private pay patient (U&C), and the ingredient cost submitted. The focus of this article is on published pricing metrics, with an example focused on NADAC. The examples given below use NADAC; however, the general process for pricing updates applies to other published pricing metrics. Other published pricing metrics may have different update cycles, frequencies of updates, and the source of pricing data may vary.

CMS publishes updates to NADAC pricing every Wednesday which includes an effective date for the pricing update. The effective date may be on, before, or after the update publication date. These data are collected by Medi-Span and incorporated into the weekly drug file sent to Utah Medicaid. Updates to the drug file are reviewed by the Utah Medicaid Pharmacy Team each Monday (or Tuesday in the case of a Monday holiday). The load date for the pricing information is the date that the full drug file is loaded and ready in the Utah Medicaid POS system by midweek, typically on Wednesday of that week (or Thursday in the case of a Monday holiday). This means that there is approximately one week from the time CMS publishes a price update until the price is updated in the Medicaid pharmacy claims adjudication system.

The date that a claim is adjudicated can affect the pricing used on that claim with regard to the date of service, the effective date of a price change, and the load date for the pricing information. The date a price is published will not impact the pricing used for adjudication, except that it impacts the load date as the load date follows the published date by approximately one week.

For example, if a claim is adjudicated after a published pricing update impacts the claim's billed NDC price, but before the new price has been loaded into the system, the claim will adjudicate at the old

price. If that same claim is reversed, then rebilled after the load date, the claim will adjudicate with the newer price, provided the date of service is on or after the new effective date. This holds true for effective dates that are before the date a pricing update has been published.

Key dates for Medicaid drug pricing metrics:

- Published Date: This is the date that the pricing metric is posted. In the case of NADAC, this is the date that CMS posts the pricing information to the CMS website.
- Effective Date: This is the date that the pricing metric goes into effect.
- Load Date: This is the date that an updated pricing metric is loaded into the Utah Medicaid point of sale system.

Process for all published pricing metrics used by Utah Medicaid:

Note: the frequency of updates for each metric represents how often the catalog of priced NDCs is updated. The pricing of a single, specific NDC will not update as frequently as the metric. For each metric, only NDCs with price changes will be modified with a pricing update.

- **NADAC**: The National Average Drug Acquisition Cost (NADAC) for a drug is published by CMS. This pricing information is determined by a contractor, currently Myers & Stauffer, who conducts optional surveys of pharmacies nationwide to approximate the average actual acquisition cost of prescription drugs nationwide. NADAC pricing updates occur once weekly.
- **FUL**: The Federal Upper Limit (FUL) for a drug is determined by CMS based on criteria published on the CMS website and in accordance with the final rule with comment (CMS-2345-FC), and is closely tied to NADAC pricing. FUL pricing updates occur once monthly near the end of the calendar month.
- **WAC**: Wholesale Acquisition Cost (WAC) is determined by manufacturers and represents the list price for a drug. The frequency of updates for WAC pricing data is dependent on the drug file vendor. Utah Medicaid currently receives drug file data from Medi-Span on a weekly basis.
- **UMAC**: The Utah Maximum Allowable Cost (UMAC) is determined by a contractor, currently Myers & Stauffer, who conducts mandatory surveys of Utah Medicaid pharmacy providers to approximate the average actual acquisition cost of prescription drugs for Utah Medicaid pharmacy providers. Myers & Stauffer publishes updated UMAC rates once weekly.

D. Dispensing Fee

A pharmacy may not charge a Medicaid member an additional fee for any service that is reimbursed as part of the dispensing fee.

For additional information about dispensing fees, refer to the Utah Medicaid State Plan, ATTACHMENT 4.19-B, Page 19a and R414-60-7.

E. Indian Health Services

Indian Health providers are reimbursed for pharmacy services in accordance with the Utah Medicaid Indian Health Provider Manual.

IX. ESRD

A. Definitions

Composite payment: A per treatment unit of payment that applies to all claims for dialysis services. The composite payment rate includes payment for all training, services, evaluations, laboratory tests, items, supplies, medications and equipment necessary to treat ESRD or perform dialysis.

Dialysis: A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

Dialysis service: The type of care or service furnished to an ESRD patient and includes all training, services, evaluations, laboratory tests, items, supplies, medications and equipment necessary to perform dialysis in a facility, outpatient, or home setting.

ESRD Facility: A facility which is enrolled with Utah Medicaid and Medicare to furnish at least one specific dialysis service. Such facilities include:

- Renal Transplantation Center: A hospital unit which is approved to furnish direct transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation center may also be a Renal Dialysis Center.
- Renal dialysis center: A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.
- Renal dialysis facility: A unit which is approved to furnish dialysis service(s) directly to ESRD patients.
- Self -dialysis unit: A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility and furnishes self-dialysis services.
- Special purpose renal dialysis facility: A renal dialysis facility which is approved to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

B. Covered services

1. Services Provided by an ESRD Facility

Dialysis services, including hemodialysis and peritoneal dialysis treatments, provided by an ESRD facility are a covered service for categorically and medically needy Medicaid members for three months pending the establishment of Medicare eligibility. Dialysis services may be covered for longer than three months if a member is not eligible for Medicare.

2. Services Performed at Home

Dialysis services, including hemodialysis and peritoneal dialysis treatments, performed at home are covered when they are supervised by an enrolled ESRD facility and performed by an appropriately trained Medicaid member.

3. Services Provided by a Non-ESRD Facility

Dialysis services, including hemodialysis and peritoneal dialysis treatments, at a Non-ESRD facility are covered when performed by an ESRD provider contracted with Utah Medicaid. The ESRD provider is responsible for billing their services and supplies during the Medicaid member's admission and stay.

C. Non-covered services

Dialysis services delivered by an ESRD facility that is not enrolled with Utah Medicaid or Medicare as an ESRD provider. Dialysis services delivered by an ESRD facility that is not in compliance with all applicable federal, state, and local laws and regulations for licensure, certification and/or registration. Individual components of dialysis services billed separately from the composite rate.

D. Limitations

Payments for dialysis services are only eligible to ESRD facilities that have enrolled with Utah Medicaid and are also enrolled with Medicare as an ESRD provider.

Dialysis services are reimbursed through a composite rate. Payment for services which are part of the composite rate are not eligible to be reimbursed separately from the composite rate.

Regardless of the dialysis method used, composite payments are limited to one unit per session and no more than one unit per day. Continuous cycling peritoneal dialysis, or any other dialysis services that occur overnight, is eligible for one composite payment.

E. Billing

The dialysis composite payment rate for all covered dialysis revenue codes is based on the Medicare ESRD Prospective Payment System base rate as identified and approved in Attachment 4.19-B on Page 12a of the Utah Medicaid State Plan.

Bill dialysis services as a UB-04 Claim using one of the following Revenue Codes. Refer to the provider manual, Section I: General Information, for detailed billing instructions or to the UB-04 Billing Manual.

Covered Dialysis Revenue Codes Revenue code 0821 (Hemodialysis) Revenue code 0831 (Peritoneal Dialysis) Revenue code 0841 (Continuous Ambulatory Peritoneal Dialysis) Revenue code 0851 (Continuous Cycling Peritoneal Dialysis)

Each dialysis session should be billed as one (1) unit for the appropriate Revenue Code and all covered dialysis revenue codes are reimbursed at the same rate. It is not necessary to bill separately for services delivered during the dialysis session that are included in the composite payment. Claim lines submitted on the UB-04 Claim for services included in the composite rate will be denied.

Procedure codes for ESRD services with accompanying criteria and limitations can be verified by using the Utah Medicaid, Bureau of Healthcare Policy and Authorization, Coverage and Reimbursement Code Lookup.

X. References

A. Utah State Plan, Attachment 4.18-C Utah State Plan, Attachment 4.19-B Social Security Act,

B. §§ 1927(d)(2) and 1927(k)(3)

C. § 1935(a)

D. 42 CFR 447.52(e) and 502

E. 42 CFR 455.410

F. 42 U.S.C. §§ 1396b (i)(23); 1396r-8; 1396r-8(g)(2)(A)

G. UCA Title 26, Chapter 18, Part 2 UCA 58-17b-606 Utah Administrative Code R414-60