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1. General Information
This manual is designed to be used in conjunction with other sections of the Utah Administrative Code R414-60. The information in this manual represents available services when medically necessary for a Medicaid member.

1.1. General Policy
This manual is updated periodically 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 e-mail notifications of policy changes and MIBs, refer to Medicaid Information Bulletins.

1.1.1. Mandatory Patient Counseling
For information regarding mandatory patient counseling, refer to R414-60-8.

1.1.2. Drug Utilization Review (DUR) Program

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Utah Medicaid Provider Manual
Division of Medicaid and Health Financing (DMHF)

Pharmacy Services
Updated April 2020

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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.

1.2. Procedure Codes

Claims for provider-administered drugs require the correct CPT or HCPCS code plus National Drug Code (NDC) as described in Section 7 of this Pharmacy Services manual.

2. Member Eligibility
For information regarding verification of a member’s Medicaid eligibility, refer to R414-60-3, or to the Eligibility Lookup Tool. Medicaid members may be referred to and enrolled in the Restriction Program. For more information please contact us: 801-538-9045 or toll free: 800-662-9651 #900.

3. Program Coverage
3.1. 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.

3.2. 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. For additional information regarding compounds, refer to R414-60-11.

3.3. Immunizations
Claims for adult Medicaid members (age 19 and older) for Hepatitis B, pneumonia, seasonal and pandemic flu, and herpes zoster vaccines administered by pharmacists can be processed through the pharmacy point of sale.

Claims for pediatric Medicaid members (age 18 and younger) for vaccines eligible through the Vaccines for Children Program may also be submitted through the pharmacy point of sale.

For additional information regarding reimbursement, refer to R414-60-7.

For Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) retro-eligible members, contact the Bureau of Medicaid Operations 1-800-662-9651 for claims payment resolution.

3.4. Diabetic Supplies
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 under Diagnostic Products.

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 in excess of 200 test strips require prior authorization using the Medication Coverage Exception Request prior authorization form.

Claims for non-preferred test strips must be submitted through the medical supply program and will not be authorized through the pharmacy point-of-sale system.

3.5. Federal Medicaid Drug Rebate Program
Utah Medicaid only covers prescription medications that are eligible to be paid for with Federal funds. In order for prescription medications to be eligible for coverage using Federal Medicaid funds, drug manufacturers must participate in the Federal Medicaid Drug Rebate Program in accordance with 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.

3.6. Mandatory Generic Drug Policy
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. For additional information regarding the mandatory generic drug policy, refer to R414-60-4.

Utah Medicaid may consult the FDA Drug Shortages database and the 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:

a. 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

b. 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 other statement that there are no commercially available preparations.

Note: Member preference does not constitute a medical necessity

3.7. Preferred Drug List (Excluding 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.

3.8. Preferred Drug List for Psychotropic Medications only
For the purposes of the Preferred Drug List (PDL), psychotropic medications are defined as the following:

- Atypical antipsychotics,
- Anti-depressants,
- Anti-convulsants/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.

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

Medicaid may potentially 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, please see Section I: General Information in Utah Provider Manual, 11-5.1 Medicare Crossover for more information.

3.10. Co-payment required for Medicaid Prescriptions
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 an Accountable Care Organization (ACO) have some drugs that are covered under Fee-for-Service (FFS) Medicaid.

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

For drugs covered by the ACO, 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.

In accordance with 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.

3.11. Days’ Supply
Unless otherwise restricted or noted below, Utah Medicaid will pay for up to a one (1) month supply of a medication per dispensing.

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 reject 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 supports 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.

The three-month supply list can be found in our resource library at https://medicaid.utah.gov/pharmacy/resource-library.

3.12. ACO Carve-Out Drugs
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
- Anti-psychotic Drugs
- Anti-depressant Drugs
- Anti-anxiety Drugs
- Anti-convulsant Drugs
- Hemophilia Drugs
- Opioid Use Disorder Treatments

3.13. 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.

4. SUPPORT Act Requirements
4.1. Opioid Policy
Utah Medicaid policy supports the Centers for Disease Control (CDC) Guidelines for Prescribing Opioids for Chronic Pain standards and encourages providers to engage in prescribing practices that support evidence-based safety standards.

4.2. 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. Please refer to the Preferred Drug List (PDL) for covered non-opioid options.

4.3. Opioid medication policies
4.3.1. Initial Fills for Short-Acting Opioids
Utah Medicaid restricts the initial fill of short-acting opioids that exceed a 7-day supply or 3 day 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.

4.3.2. Quantity Limits
Please refer to the Drug Criteria and Limits attachment for monthly quantity limits of opioid medications.

4.3.3. Morphine Milligram Equivalents (MME) and cumulative Morphine Equivalents Daily (MED)
Utah Medicaid uses MME and cumulative daily MED methodology when adjudicating all opioid claims for the treatment of non-cancer pain.
   a. 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:
      o 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
      o 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.
   b. July 1, 2019, the 180 MED threshold was reduced to 150 MED
   c. January 1, 2020 the 150 MED threshold was reduced to 120 MED

4.3.4. 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. 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. This days’ supply limit can be overridden when a valid “cancer pain diagnosis code” is placed on the claim. For all opioid claims billed for 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 prior to 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 reject.

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. Prior authorization forms for opioid medications can be obtained from the Pharmacy Prior Authorization web page, https://medicaid.utah.gov/pharmacy/prior-authorization.

4.3.5. Concurrent Use of Opioids with Benzodiazepines

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 recommend against combined use, which is associated with 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, in accordance with 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)

a. July 1, 2019: Concurrent prescribing of long-acting opioid medications and benzodiazepines will be 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 reject. Likewise, if a paid claim for a long-acting opioid is found, the benzodiazepine claim will reject. 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.

b. 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 appropriate use
✓ Proactively outreach to prescribers to consider other, safer combinations

4.3.6. 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. 2 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.

4.4. Medication-Assisted Treatment for Opioid Use Disorder
The Utah Medicaid PDL includes medications used for the treatment of opioid use disorder. Please refer to the PDL for coverage options.

4.5. 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 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) prior to 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 exceed the pre-established limits will reject at the pharmacy point of sale and require a prior authorization.

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

5. Outpatient Cancer Therapy
Utah Code 58-17b-805 allows for prescribing practitioners to dispense medications to their patients in lieu of having the prescriptions filled at a pharmacy. Utah Medicaid will reimburse a prescribing practitioner that dispenses medications pursuant to this law if they register with Utah Medicaid as a pharmacy and submit electronic point-of-sale claims.

6. Non-Covered Services and Limitations
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.

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

6.2. Limitations
For a listing of limitations, Drug Criteria and Limits and Opioid Quantity Limits Complete List, refer to the Utah Medicaid Resource Library and R414-60-5.

6.3. Refills and Early Refills
Utah Medicaid will pay for a prescription refill only when 80% of the previous prescription has been exhausted, with the exception of opioid analgesics and controlled substances. 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 will establish 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 Medicaid member, or the member’s agent, based on continued medical necessity. Automatically refilled prescriptions, or cycle filled prescriptions, are not eligible for reimbursement.

Utah Medicaid will only pay for an early refill of a medication in cases of lifesaving necessity. Utah Medicaid will not pay for an early refill in the following circumstances:
- a. Member preference for a particular brand-name or generic version of a drug or vice versa;
- b. Lost, stolen, or destroyed prescriptions;
- c. Early refills to accommodate travel (a.k.a. “vacation refill”);
- d. Prescriptions that have not been used according to the prescribed directions;
- e. Refills for Medicaid members entering, or leaving, a long-term care facility, including “take-home” supplies when a Medicaid member is temporarily leaving a nursing home facility.

6.4. Blood Factors and Hemophilia 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, in accordance with 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 trainings.

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

7. 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 a 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 timely filing. Repeat issues may be referred to OIG for further investigation in accordance with Utah Code Section 63A-13-3.

7.1. Prior Authorization
Pharmacy prior authorizations must be initiated by a Medicaid prescriber. For additional information regarding pharmacy prior authorizations, refer to R414-60.

7.2. 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.
7.3. 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.

7.4. National Prescriber Identifier Requirement on Pharmacy Claims

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.

7.5. Provider Administered Drug (Pharmacy HCPCS or CPT Codes)

7.5.1. Billing Pharmacy 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 Coverage and Reimbursement, Coverage and Reimbursement Code Lookup Tool. Covered NDC’s can be verified by using the Utah Medicaid, Bureau of Coverage and Reimbursement, 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 Coverage and Reimbursement Policy, Coverage and Reimbursement Fee Schedule Download, HCPCS/NDC Crosswalk.

If the submitted combination is unmatched, the claim will deny. 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 denying. 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 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 drug 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.

7.6. 340 B Billing
Covered entities participating in the 340B Program must comply with all 340B Program requirements (https://www.hrsa.gov/opa/program-requirements/index.html). States have an obligation to 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. 340B covered entities can be sanctioned for causing duplicate discounts or drug diversion (42 U.S.C. § 256B).

Each 340B 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 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.

7.6.1. Outpatient Pharmacy (Point-of-Sale) Billing
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’s 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.

7.6.2. Provider Administered Drug (J-Code) Billing

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.

<table>
<thead>
<tr>
<th>Hospital Type (determined by CMS)</th>
<th>Pass-through Drug (SI “G”)</th>
<th>Separately Payable Drug (SI “K”)</th>
<th>Vaccine (SI “F” “L” or “M”)</th>
<th>Packaged Drug (SI “N”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Paid under OPPS</td>
<td>TB, Optional</td>
<td>TB, Optional</td>
<td>N/A</td>
<td>TB or JG, Optional</td>
</tr>
<tr>
<td>CAH</td>
<td>TB, Optional</td>
<td>TB, Optional</td>
<td>N/A</td>
<td>TB or JG, Optional</td>
</tr>
<tr>
<td>Non-Excepted Off-Campus PBD</td>
<td>TB</td>
<td>TB</td>
<td>N/A</td>
<td>TB or JG, Optional</td>
</tr>
<tr>
<td>Paid under the OPPS, Excepted from the 340B Payment Adjustment for 2018</td>
<td>TB</td>
<td>TB</td>
<td>N/A</td>
<td>TB or JG, Optional</td>
</tr>
</tbody>
</table>

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 following providers:

7.7. Utah Maximum Allowable Cost and NADAC

For information regarding the Utah Maximum Allowable Cost (MAC), refer to R414-60-7.

For questions or concerns regarding NADAC pricing, please contact: Myer’s National Average Drug Acquisition Cost (NADAC) Help Desk (855) 457-5264 info@mslerps.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

7.8. Dispensing Fees

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 refer to R414-60-7.

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

8. End Stage Renal Disease (ESRD)
Dialysis services are provided under the Utah Medicaid State Plan to cover Medicaid members principally for the three (3) month period between the first dialysis service and commencement of the Medicare End Stage Renal Disease (ESRD) benefit. The Medicaid State Plan also allows for coverage of dialysis services for Medicaid members who do not qualify for Medicare coverage. ESRD facilities are required to assist Medicaid members in applying for and pursuing final Medicare eligibility during the first three (3) months of providing dialysis services.

An ESRD facility may be reimbursed by Utah Medicaid for providing dialysis services only if the ESRD facility is enrolled with Utah Medicaid and Medicare as an ESRD provider. The ESRD facility must be in compliance with applicable federal, state, and local laws and regulations for licensure, certification and/or registration.

A non-ESRD facility will need to identify an ESRD provider that is contracted with Utah Medicaid to provide services during Medicaid member’s admission and stay. This contracted ESRD provider will bill Utah Medicaid for ESRD services rendered during the stay.

8.1. Definitions for ESRD
Definitions specific to ESRD services are provided below.

8.1.1. 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.

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

8.1.3. 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.

8.1.4. End Stage Renal Disease (ESRD)
That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

8.1.5. 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 directly 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.

8.2. Covered Services for ESRD

8.2.1. 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.

8.2.2. 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.

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

8.3. Non-Covered Services and Limitations for ESRD

8.3.1. 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 a 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.

8.3.2. Limitations
Payment 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 occurs overnight, is eligible for one composite payment.

8.3.3. Billing for ESRD Services
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 ERSD services with accompanying criteria and limitations can be verified by using the Utah Medicaid, Bureau of Coverage and Reimbursement, Coverage and Reimbursement Code Lookup.

9. Biologic Medications and Substitution 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. In order 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 in order 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-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-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. Currently there are 23 biosimilars and zero 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.

10. References
Utah State Plan, Attachment 4.18-C Utah State Plan, Attachment 4.19-B Social Security Act, §§ 1927(d)(2) and 1927(k)(3)
§ 1935(a)
42 CFR 447.52(e) and 502
42 CFR 455.410
42 U.S.C. §§ 1396b (i)(23); 1396r-8; 1396r-8(g)(2)(A)
UCA Title 26, Chapter 18, Part 2 UCA 58-17b-606 Utah Administrative Code R414-60