

SECTION 2

PHARMACY MANUAL

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1 GENERAL POLICY

The Utah Department of Health, Division of Medicaid and Health Financing (DMHF) covers most medications prescribed by qualified practitioners as a Medicaid benefit, in compliance with Federal law (42 CFR 440.120). All drugs or products must have a NDC number. [Social Security Act, Section 1927 (K)(3)] Medicaid covers legend drugs with some exceptions and restrictions outlined in Omnibus Budget Reconciliation Act (OBRA) 1990 and 1993 and further identified in this manual, some over-the-counter products, and generic products. This manual is updated by Medicaid Information Bulletins (MIBs) published on the Medicaid Website. (The Amber Sheet, a publication of the Drug Utilization Review (DUR) Board, is not an official Medicaid publication; it contains general information and educational items.)

1 - 1 Legal References

Utah Code Title 58-17b-606 mandates that when a multisource legend drug is available in the generic form, the Medicaid Agency may only reimburse for the generic form of the drug unless the treating physician demonstrates a medical necessity for dispensing the non-generic, brand-name legend drug. Medicaid Agency pharmacists may override the generic mandate provisions if a financial benefit will accrue to the state. The Division of Medicaid and Health Financing requires all pharmacies to dispense generically within the intent and guidelines listed in this law and under the conditions established.

1 - 2 Federal Upper Limit List *(Updated 4/1/12)*

The Centers for Medicare and Medicaid Services (CMS), through the Federal Upper Limit Bureau, provides a biyearly list to the State Medicaid agency which contains the mandated generic, multi-source level of reimbursement for the identified drugs. The Federal Upper Limit (FUL) List is generally reissued January 1 and July 1. A data provider, under contract to Utah Medicaid, maintains these pricing regulations on the Utah Master Reference File.

The Patient Protection and Affordable Care Act of 2009 (PPACA) established a new methodology for determining FULs. CMS has not fully implemented these new guidelines. For further information, please go to: <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits-.html>. Medicaid will continue to publish information as it becomes available.

Generic substitution may only be made with products with an A B rating identified in the Approved Drug Products (orange book) published by the U. S. Department of Health and Human Services. The Federal Upper Limit information is available through the Medicaid Point of Sale system and on the Internet at: http://www.cms.gov/Reimbursement/05_FederalUpperLimits.asp

The reimbursement currently allowed by CMS is determined by 150% of the average of the lowest three products in the multi-source class. The purchase of all generic products from a single manufacturer may leave some products unavailable at the FUL level. Although a pharmacy may choose not to stock multiple brands and has only products more costly than the FUL, a Medicaid client may NOT be charged the difference between the FUL and the pharmacy cost.

A pharmacy may not dispense a house brand generic product and bill Medicaid for an NDC of a name brand or generic brand product. The name or manufacturer or NDC for the product dispensed must be recorded on the prescription.

Medicaid cannot override a FUL price. A DAW option is not available to override a FUL.

Pharmacy Reimbursement

Utah Medicaid reimbursement is outlined in the State Plan, Section 4, 19-B, Section S, and may be viewed online at http://www.health.utah.gov/medicaid/stplan/A_4-19-B.pdf. Pharmacies must submit their lowest usual and customary charges to Medicaid, including promotional rates such as \$4.00 generics, if they are offered to the general public.

1 - 3 Utah MAC List *(Updated 4/1/12)*

The Division of Medicaid and Health Financing (DMHF), Bureau of Coverage and Reimbursement, maintains the Utah Maximum Allowable Cost (MAC). A current list of State MAC prices will be posted on the Medicaid Pharmacy Services Website at <http://health.utah.gov/medicaid/pharmacy/coverage/directory.php>.

MAC prices may be used with certain categories of drugs and may be applied to each drug in the category. In these cases, both brand name and generic elements of the class may be classed as preferred agents. If the class is not part of a preferred drug list (PDL), MACs may be applied to just the generic drugs of the class. In these cases, a brand name prior authorization will be required in order to be reimbursed for the brand name drugs. No DAW option is available to override a MAC price. MAC prices may be used on drug categories that have FUL prices.

Non-Traditional Medicaid and Primary Care Network (PCN) note: Brand name prior authorizations are not available for Non-Traditional and PCN clients. They are responsible for 100% of the cost when brand name drugs not on the PDL are dispensed. Please see the Non-Traditional and PCN policy manuals for specifics.

1 - 4 New Products *(Updated 4/1/12)*

Any new legend drug product, new size of an existing approved product, or new strength of an existing approved product may be reimbursable, subject to Medicaid limitations and/or prior approval. New drugs will be reviewed for limitations such as prior approval, quantity, and frequency. New drugs may be withheld from coverage for no more than twelve weeks while restrictions or limitations are being evaluated.

In many cases, new drugs are new members of a class of drugs currently subject to prior approval, quantity, or frequency limitations. In these cases, if a twelve week evaluation is deemed unnecessary, the new drug may be immediately reimbursable under the same limitations to which other members of the class are subject.

New drugs may also be reviewed for off-label or experimental uses. Refer to Chapter 2 - 1, Formulary.

1 - 5 Clients Enrolled in a Managed Care Plan

*A Medicaid recipient enrolled in a managed health care plan (MCP), which includes pharmacy services, must receive all pharmacy services through that plan. A MCP may designate a particular provider as the ONLY provider approved by the MCP to receive payment for services to an enrolled Medicaid recipient.

A provider must be affiliated with the client's managed care plan in order to receive payment for services. Each plan may offer different benefits and restrictions than the Medicaid scope of benefits. The plans which include pharmacy services specify which are covered, which require prior authorization, the process to request authorization and the conditions for authorization. All questions concerning services covered by or payment from a managed care plan must be directed to the appropriate plan.

Reference: Utah Medicaid Provider Manual, SECTION 1, GENERAL INFORMATION: Chapter 4, Managed Care Plans; Chapter 5, Verifying Eligibility - how to verify a patient's Medicaid eligibility and possible enrollment in a managed care plan.

*NOTE: Since November 1997, none of the Medicaid MCP's have covered pharmacy services. All pharmacy services are fee-for-service.

1 - 6 Fee-for-Service Clients

A **fee-for-service** client is a Medicaid client who is either (1) not enrolled in a managed care plan or (2) *is enrolled in a managed care plan in which pharmacy benefits are not included ('carved out'). Fee-for-service clients, with the exception of clients in the Restricted Program, may receive pharmacy services from any pharmacy provider who accepts Medicaid.

Effective October 1, 2011, Utah Medicaid will no longer accept a client Social Security number on pharmacy point of sale claims. Medicaid pharmacy claims will need to be billed using the Medicaid Client Identification Number found on the Medicaid Identification Card. Client Identification Numbers can also be obtained by calling Access Now at (801)538-6155 or (800)662-9651, and selecting options 1 and 1 on the phone tree.

You should **REQUIRE** the client's proof of eligibility **BEFORE** you provide service and **EACH TIME** you provide service. Proofs of Medicaid eligibility are the Medicaid Identification Card or Interim Verification of Medicaid Eligibility. Proof of eligibility for the Baby Your Baby Program is the Baby Your Baby Card. Look carefully at the dates of eligibility on the client's card. If the card is hand-written, you may wish to copy the card to substantiate your Medicaid claim. Medicaid does not pay claims for services after the client's eligibility expires.

The Medicaid Point of Sale system 'captures' a claim even when the computer system has no information as to the client's eligibility. The system returns the message 'claim captured' to advise the pharmacy the claim has been received by Medicaid. The message 'claim captured' does NOT guarantee payment. If the system is subsequently updated, and the claim is within the client's dates of eligibility, it may be paid. If eligibility information is not posted to the Point of Sale system, the claim will be denied. You will NOT receive payment for the services given to the client unless you have a copy of the proof of eligibility the client presented at the time of service which verifies eligibility on the date of service.

Reference: SECTION 1, GENERAL INFORMATION: Chapter 3 - 2, Restricted Program; Chapter 5, Verifying Eligibility - how to verify a patient's eligibility and possible enrollment in a managed care plan.

Client Identification Numbers Ending in 'V' or 'X'

Clients whose number ends in 'V' have a Baby Your Baby Identification Card. Clients whose number ends in 'X' have an Interim Verification of Eligibility (Form 695). You may wish to copy the card or form to substantiate your Medicaid claim. When a temporary proof of eligibility expires, Medicaid will no longer pay claims, unless the client has since been issued a Medicaid Identification Card for the month of service.

Expiration Date on Baby Your Baby Card

A woman eligible for a Baby Your Baby Card is told to present the Card **each time** she requests prenatal services. The card has an **initial expiration date** pending a formal decision of eligibility for Medicaid. If a determination of Medicaid eligibility cannot be made before the initial card expires, the **Medicaid eligibility worker may extend** the expiration date on the card.

Expiration Date on Interim Verification of Medical Eligibility (Form 695)

An "Interim Verification of Medical Eligibility" (Form 695) with date limits may be issued by the Medicaid eligibility worker when a client needs proof of eligibility and does not yet have the Medicaid Card.

1 - 7 Quality Improvement Programs

The State Drug Utilization Review Board will use Retrospective Drug Utilization Review (RetroDUR) studies to review prescribing and dispensing patterns for Medicaid patients. The Board is comprised of providers nominated by the Utah Medical Association, the Utah Pharmaceutical Association, and the Utah Dental Association.

RetroDUR studies are authorized by the Omnibus Reconciliation Act (OBRA) of 1990. The University of Utah College of Pharmacy collaborate on the development of drug criteria sets under contract with the Division of Medicaid and Health Financing. Academicians from the School of Medicine and the School of Pharmacy review the sets with the Drug Utilization Review (DUR) Board.

To order a copy of drug criteria sets, please contact the Medicaid pharmacy program for more information.

1 - 8 Co-payment Required for Medicaid Prescriptions

Effective February 1, 2003, most Medicaid recipients are required to pay a \$3.00 co-payment for each prescription filled. **The Point of Sale system informs you when a co-payment is due.** When Point of Sale (POS) shows a \$3.00 co-payment, the Medicaid recipient is expected to pay the \$3.00 in order to receive the prescription. There is a \$15.00 monthly maximum on co-payment in the Traditional Medicaid Program.

1. Recipient Notification

Medicaid recipients who are required to pay the co-payment receive a Medicaid Card which states 'Co-payment required for pharmacy'.

2. Exempt Recipients

Some Medicaid recipients are exempt from the pharmacy co-payment, due to age or other specific criteria. Point of Sale will not indicate a co-payment when the recipient is exempt.

- A. When any or all of the recipients listed on the Medicaid Card are required to pay the co-payment, the Card will have the 'Co-payment required' message. Because a family eligible for Medicaid may contain adults required to make a co-payment and children who are exempt from the requirement, you must use Point of Sale to know whether the patient with a prescription has a co-payment or not.
- B. When all of the recipients listed on the Medicaid Card are exempt, the Card will NOT have the message 'Co-payment required for pharmacy'.

For your information, the following groups of Medicaid recipients are exempt from the co-payment requirement:

- (1) Recipients enrolled in a MCP that includes prescription drug coverage, with one exception for protease inhibitors as described in paragraph number 5. NOTE: As of November 1997, none of the Medicaid MCP's covers pharmacy services. All pharmacy services are fee-for service.
- (2) Children under age 18.
- (3) Residents of a nursing home who are entitled to keep only the \$45 personal need allowance.
- (4) Pregnant women, as determined by the Medicaid eligibility worker.

- (5) Recipients whose monthly household income is less than the payment amount in the Family Employment Program, as determined by the Medicaid eligibility worker.
- (6) American Indian/Alaska Native.
- (7) Recipients with prescriptions for family planning. Prescriptions for family planning, such as birth control pills, will NOT indicate a co-payment.

3. Maximum \$15.00 a month Co-payment for Each Recipient in the Traditional Medicaid Plan

Once a recipient has met an individual maximum co-payment of \$15.00 a month for his or her prescriptions, Point of Sale will NOT indicate a co-payment is due. Medicaid will keep track of the cumulative number of prescriptions for a recipient with \$3.00 co-payments. Once five prescriptions with \$3.00 co-payments have been filled, Point of Sale will no longer indicate a \$3.00 co-payment. Reversal of a previously filled prescription with a co-pay will require a refund of the co-pay to the individual, and will cause the next prescription filled for that recipient to be adjudicated with a co-pay.

4. Recipients with Temporary Proof of Eligibility

When the client has an interim Form 695, Verification of Medicaid Eligibility, and the Point of Sale system (POS) does not yet display Medicaid eligibility information, we ask that you do **NOT** collect a co-payment unless the form is stamped 'Co-payment REQUIRED.' (To ensure reimbursement when a client's number ends with letter 'X', ALWAYS require the client's proof of eligibility.) The Medicaid eligibility worker will add the statement 'Co-payment REQUIRED' to the top of the Form 695 when applicable for the adults listed on the form. A co-payment should **never** be collected when dispensing prescriptions for children who are under age 18.

In addition, we recommend you do **NOT** require a co-payment when the prescription is for family planning, such as birth control pills.

Please note the pharmacist cannot exempt the co-payment on the basis of pregnancy or household income. These exemptions can only be determined by the Medicaid eligibility worker.

Typically, POS receives eligibility information overnight. When the pharmacy claim is entered the day after the initial determination of Medicaid eligibility, the co-payment indicator will state whether \$3.00 will be subtracted from the reimbursement amount.

When POS displays eligibility information for the client, **you must use Point of Sale** to determine when to collect a co-payment, regardless of whether the Form 695 has a copay message or not. Once a Medicaid Identification Card has been issued, POS determines when a co-payment is due, even though the client may be using a Form 695 as a substitute for a missing Medicaid Card.

5. Baby Your Baby Program

NEVER collect a co-payment from a client eligible for the Baby Your Baby Program on the date of service. A copayment will **NOT** be assessed by Medicaid. When a client's number ends with letter 'V', ALWAYS require the Baby Your Baby Card and CHECK THE DATES OF ELIGIBILITY.

QUESTIONS?

When Point of Sale is not available, and you cannot determine whether a co-payment is due or not, you may call Medicaid Information. In the Salt Lake City area, call 801-538-6155. In other areas of Utah, call toll-free 1-800-662-9651.

If a Medicaid recipient has a question about whether he or she is exempt from the co-payment, the recipient should contact his or her eligibility worker. If the recipient has a question about being charged a co-payment, whether for a certain type of prescription or being charged for more than five prescriptions in a month, he or she should discuss this with the pharmacist. If the recipient continues to have questions or concerns, he or she should talk to the eligibility worker.

1 - 9 Internet Access to Medicaid Manuals

SECTION 2 of this Medicaid Provider Manual is accessible on the Internet. Go to the Medicaid website at <http://health.utah.gov/medicaid> and choose the link to “manuals”. The most recent edition of the manual and attachments can be accessed, as well as the past two years in archives.

1 – 10 Tamper Resistant Prescription Pad Requirements

In May 2007, Congress passed a bill requiring that written prescriptions for drugs under the Medicaid program must be on tamper-resistant prescription pads.

Effective April 1, 2008, all new written Medicaid prescriptions (except those for residents of nursing facilities, intermediate care facilities for the mentally retarded (ICF/MR), or other specified institutional and clinical settings) must be written on tamper-resistant prescription pads. The following requirements are mandated:

1. Applies only to written prescriptions. Prescriptions that are electronic (those that are faxed, taken over the phone, or transmitted through other electronic means) are not covered under this law.
2. Applies only to new prescriptions filled on or after April 1, 2008. Does not apply to refills of prescriptions initially filled prior to April 1, 2008, until law requires a new prescription.
3. Compliance with all federal and state laws regarding the types of documentation and how prescriptions are filled must be maintained.

If a pharmacy fills a prescription that does not comply with the requirements above, funds paid by Medicaid will be recovered. Prescribers will have to ensure that pads used to write Medicaid prescriptions meet the following requirements in order to be considered “tamper-resistant”. If not, the patient will likely be sent back to get another prescription written on a compliant prescription form.

Effective April 1, 2008, the prescription form must contain at least one of the following three characteristics:

1. One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
2. One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber;
3. One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Effective October 1, 2008, to be considered tamper-resistant, a prescription pad must contain all three of the above characteristics.

1 - 11 Correct Prescriber Identifier Requirement on Pharmacy Claims

Utah Medicaid requires the correct prescriber NPI to be submitted on all pharmacy claims. Claims submitted without the appropriate prescriber NPI will be denied.

1 - 12 Dual Eligible Clients

Outpatient drugs covered under Medicare Prescription Drug Benefit Part D for full-benefit dual eligible beneficiaries (who are defined as individuals who have Medicare and full Medicaid coverage), will not be covered under Medicaid in accordance with SSA 1935(a). Medicaid recipients with dual coverage of both Medicaid and Medicare receive a limited drug benefit through Medicaid. They receive the majority of their drugs through Medicare Part D. Drugs excluded under Medicare Part D are not covered for dual eligible recipients, except for certain limited drugs which are provided, in accordance with SSA, Section 1927(d)(2), to other Medicaid recipients including those who are full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit Part D. Medicaid will cover certain over-the-counter drugs, certain cough and cold preparations, barbiturates, and benzodiazepine drugs. Coverage for these can be determined through the Medicaid point of sale system using the same limitations and criteria that apply to all Medicaid clients.

2 COVERAGE OF SERVICES

When a client wants medications not covered by the Medicaid program, the client may choose to pay for the non-covered medications. For information on the circumstances in which a client may be billed for non-covered Medicaid services, refer to the SECTION 1 of this manual, Chapter 6 -8, Exceptions to Prohibition on Billing Patients, item 1, Non-Covered Services.

2 – 1 Formulary (Updated 4/1/12)

OBRA 1993, Section 1927 (d) (6) states: “Effective October 1, 1993, states may exclude, restrict, or subject to prior authorization new drugs approved by the Food and Drug Administration (FDA).” However, Utah law prohibits Utah Medicaid from having a closed formulary. Utah Medicaid maintains an “open” formulary with a few drug classes not covered as allowed by OBRA and Utah Law.

During the 2007 legislative session, the Utah State Legislature passed Senate Bill 42 allowing Medicaid to adopt a preferred drug list (PDL). Medicaid began to phase in the PDL in October of 2007.

A Pharmacy and Therapeutics (P&T Committee), consisting of an academic pharmacist, a hospital pharmacist, a chain store pharmacist, an independent pharmacist, a government pharmacist, a pediatrician, a family practice physician, a psychiatrist, and an internist, will advise the DUR Board and Medicaid in choosing preferred agent(s) for each selected class of drugs based on safety and clinical efficacy.

Continual public updates about the PDL implementation process will be provided through the Amber Sheet, MIB, and Pharmacy Services web site at <http://health.utah.gov/medicaid/pharmacy> .

During the 2009 legislative session, the Utah Legislature passed Senate Bill 87, which authorizes Utah Medicaid to require a prior authorization for non-preferred drugs. The PA requirement became effective May 18, 2009.

Non-Preferred Authorization (NPA) will be granted to clients who meet one or more of the following criteria:

- Trial and failure of at least one preferred agent in a class. Medicaid will require the name of the preferred product(s) tried, length of therapy, and reason for discontinuation.
- Evidence of a potential drug interaction between current medication and the preferred product(s).
- Evidence of a condition or contraindication that prevents the use of the preferred product(s).
- Objective clinical evidence that a patient is at high risk of adverse events due to a therapeutic interchange.

Requests for NPA can be faxed to (855) 828-4992. The appropriate form can be obtained online from the Pharmacy Services website at <http://health.utah.gov/medicaid/pharmacy>.

2 - 2 Prescribed Legend Drugs

A. Prescribed legend drugs are covered with the following limitations:

1. Non-covered drugs which are listed in Chapter 2-3, Non-covered Drugs and Services.
2. Drugs which require prior approval.
3. Drugs by manufacturers who have not entered into a rebate agreement with CMS.
4. Nutritional substances.
5. Metabolic nutritional products.

B. Off-Label, Experimental and Investigational Drugs

The Utah Medicaid Program restricts the covered drug products on the open formulary to uses approved and documented by the officially recognized compendia [OBRA 1993, section 1927 (d) (6)]. The designated compendia are:

1. Package insert, FDA approved uses
2. American Hospital Formulary Service Drug Information (AHFS)
3. American Medical Association Drug Evaluation (AMADE)
4. United States Pharmacopeia Drug Information Drug Information (USP- DI)
5. DRUGDEX

Off-label Use

The Drug Utilization Review (DUR) Board may approve, for a specific case, an unlisted off-labeled use for a given drug if the off labeled use meets ALL of the following criteria.

1. Use must be diagnosis specific as defined by an ICD-9 code (s).
2. Off-labeled use must be supported by one major multi-site study or three smaller studies published in JAMA, NEJM, Lancet or peer review specialty medical journals such as Journal of Cardiology. Articles must have been published within five years.
3. Off-labeled use must have a defined dosage regimen.
4. Off-labeled use must have a defined duration of treatment.
5. The off-labeled use shows clear and significant clinical or economic advantage over existing approved drug regimens.

Experimental Use

Experimental use is defined as drug use for indications not supported by FDA or published studies. Drugs prescribed for experimental use are not covered. Experimental drugs or herbal products are not covered. As documentation accumulates for a given indication, the experimental drug use may move to the off-label category or be approved as a labeled indication, as determined by the DUR Board.

Investigational Use

Investigational drugs or chemicals are not covered. Any drug or chemical that does not have an NDC number is deemed investigational.

The UMA, Utah based Group Practices or Utah based prescribers have the option of petitioning the DUR Board for coverage for an unlisted, off-labeled use of a given drug. The petitioner(s) must schedule an appearance before the Board to present the case for the petitioned drug. Petitioners must provide documentation including one published major multi-site study or a minimum of three recent (five years) articles from JAMA, NEJM, Lancet or peer review specialty medical journals such as the Journal of Cardiology, supporting the petition's position. If possible, the documentation must be submitted two weeks in advance of the scheduled DUR Meeting.

2 – 3 Non-covered Drugs and Services *(Updated 4/1/12)*

Only drugs and services described previously as covered are reimbursable by Medicaid. This chapter summarizes those products and services which are not covered, and their exceptions, if any.

The Social Security Act, Section 1927 (d) (2) states: "The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted by a state participating in the master rebate agreement."

1. Agents when used for anorexia, weight loss or weight gain.
2. Agents when used to promote fertility.
3. Agents when used for cosmetic purposes or hair growth.
4. Agents when used for the symptomatic relief of cough and colds.
5. Agents when used to promote smoking cessation.
6. Vitamins, except when provided for:
 - Pregnant women: prenatal vitamins with folic acid (prenatal vitamins are not covered post-delivery)
 - Children through age five: children's vitamin drops with or without fluoride
 - Adults and children of all ages: fluoride supplement
7. Nonprescription drugs (over-the-counter, or OTC).
8. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests and monitoring services are purchased exclusively from the manufacturer or its designee.
9. Barbiturates

10. Benzodiazepines
11. Agents used for the treatment of sexual or erectile dysfunction.

However, Utah Medicaid has chosen to include phenobarbital, benzodiazepines, a limited selection of cough and cold products, a limited list of OTC drugs, and products for smoking cessation. In accordance with Section 4107 of the Patient Protection and Affordable Care Act (P.L. 111-148) that was effective October 1, 2010, Utah has chosen to cover both OTC and prescription smoking cessation products. Utah has also chosen to exclude coverage of drugs available only through unique, single-source distribution programs.

Beginning July 1, 2007, only the following legend cough and cold preparations will be available for coverage through the Medicaid program:

Legend cough and cold agents used for symptomatic relief:

- Guaifenesin with DextroMethorphan (DM) 600/30 tab
- Guaifenesin with Hydrocodone 100/5 liquid
- Promethazine with Codeine
- Cheratussin AC
- Rondec and Rondec DM (generic equivalents only)

Covered over-the-counter cough and cold remedies are given in the approved OTC list.

In addition, the following are not covered benefits:

- A. Any drug without a prescription, including over-the-counter drugs, is not a benefit.
- B. Any drug or product for which an NDC number is not available is not a Medicaid benefit. [Social Security Act, Section 1927 (K)(3)]
- C. Over-the-counter drugs not on the approved Over-the-counter Drug list are not a Medicaid benefit.
- D. Certain OTC drugs on the approved list are not a benefit for a Medicaid client who is a resident of a nursing home. When this restriction on a drug is indicated, all dosage forms apply.
- E. Early refills of prescriptions are not a Medicaid benefit except as specified in Chapter 4 - 7, Early Refills.
- F. Drug classes not covered as allowed by OBRA and Utah Law are not a Medicaid benefit.
- G. Off-Label Drug Use is not a Medicaid benefit. Only uses approved as described in Chapter 2 - 2, Prescribed Legend Drugs, item B, are covered by Medicaid.
- H. Less-Than-Effective (DESI) Drugs are not a Medicaid benefit.

As stated in Chapter 5 - 4, Desi Drugs, drugs are classified into five groups. Drugs in groups 4, 5, and 6 are NOT covered by Medicaid. DESI drugs are combinations of products and single products that, in the Federal Drug Efficacy Study Information (DESI), have not been proven to CMS to be effective for the conditions indicated in the information packet.

- I. Drugs given by a hospital to a patient at discharge (take-home drugs) are not a Medicaid benefit.
- J. Breast milk substitutes are not a Medicaid benefit.

- K. Multiple vitamins (except for prenatal vitamins with folic acid for pregnant women, and multiple vitamins with or without fluoride for children through age 5) are not a Medicaid benefit.
- L. Baby food is not a Medicaid benefit.
- M. New pharmaceutical products on the market are often covered by the Medicaid Physician Program and not covered by the Pharmacy Program. These are typically physician-administered drugs given only by injection.

Also, some products removed from coverage by the Pharmacy Program continue to be available through the Physician Program.

- N. Prescriptions for medication for erectile dysfunction are not a covered benefit.

2 – 4 Prescribed Over-the-Counter Products

Over-the-Counter drugs (OTC) are covered ONLY when (1) the drug is listed on the Medicaid-approved OTC List and (2) the drug is ordered on a prescription. **The OTC list is included with this manual.** See ATTACHMENTS. OTC drugs are identified in OBRA 1990 as a category that a state may choose not to cover. Utah has chosen to include as a benefit a limited list of over-the-counter products. This list is reviewed twice a year for changes, additions, or deletions. Changes to the list are published in the Medicaid Information Bulletin.

Only the Over-the-Counter drugs on the latest list published in the Medicaid Information Bulletin (MIB) are reimbursable. No other formulas or similar products are a benefit.

1. OTC drugs NOT on the approved list are NOT covered.
2. Certain OTC drugs on the approved list are not a benefit for a Medicaid client who is a resident of a nursing home. When this restriction on a drug is indicated, all dosage forms apply.
3. Limits and criteria may also be noted on the OTC list after the drug name.
4. Excessive utilization or waste may cause the whole class to be dropped from the program.
5. OTC drugs are not covered for manufacturers who have not entered into a rebate agreement with CMS.

2 – 5 Generic Preparations

Medicaid requires use of generic drugs, unless the physician obtains a prior approval for the brand name drug. However, Medicaid does not pay for generic house-brand or store brand products unless the manufacturer has entered into a rebate agreement for each specific NDC number. Manufacturers that have not entered the federal rebate program will not have their products covered. This includes almost all 'house brand' and 'store brand' products.

In a very few limited instances, manufacturer rebates can create situations where the brand name version of a drug may cost less. These situations are rare and will be investigated by the pharmacy program managers. When substantiated, Medicaid may reimburse for that brand product as a cost saving measure after evaluation reveals that the savings will be maintained for the program. These exceptions will be subject to strict requirements on the part of

manufacturers. Coverage extended will undergo continuous re-evaluation, and notice will be provided if and when these instances occur.

Medicaid clients may receive brand name Tegretol, Dilantin, and Coumadin without prior authorization due to the narrow therapeutic index of these drugs.

3 PRIOR APPROVAL *(Updated 4/1/12)*

Prior Authorization (PA) is an approval given by the Medicaid agency, prior to services being rendered. Approval must be obtained precedent to service being provided. PA confirms that services requested are needed and reimbursable by Medicaid, that they conform to commonly accepted medical standards, and that all less costly or more conservative alternative treatments have been considered. PA does not guarantee reimbursement. All other Medicaid requirements must be met in order for a provider to receive reimbursement.

- A. Prior Authorization (PA) requirements apply ONLY for services which may be covered directly by Medicaid. These include services for a patient assigned to a Primary Care Provider or services not included in a contract with a managed care plan.
- B. The PA requirements and process do not apply for services covered by a managed care plan when the Medicaid patient is enrolled in that managed care plan. Each plan specifies which services it covers, which require authorization, and the conditions for authorization. Because information as to what plan the client must use is available to providers, the provider must follow the plan's procedures for authorization in order to receive reimbursement.

*Medicaid cannot process requests for PA for services included in a contract with a managed care plan. Providers requesting services for a client enrolled in a managed care plan will be referred to that plan. Even if a PA is erroneously given by the Medicaid fee-for-service staff, those authorizations will not be valid if the provider failed to obtain an appropriate authorization from the managed care plan identified on the card.

*IMPORTANT NOTE: Since November 1997, none of the Medicaid MCP's have covered pharmacy services. **All pharmacy services are fee-for-service.** Physician services, including physician administered drugs are covered under the managed care plans. They are **not** pharmacy services.

- C. If a provider is required to obtain PA, fails to do so, provides service anyway, and then bills Medicaid, Medicaid must deny the claim. Because it was the provider's responsibility to obtain authorization, the provider is prohibited from subsequently billing the patient for the unpaid service. Refer to SECTION 1, Chapter 6-7, Medicaid as Payment in Full; Billing Patients Prohibited.
- D. There are specific, limited exceptions to the requirement that approval must be obtained BEFORE service being provided. The exceptions are explained in and limited by Chapter 3-4, Retroactive Authorization.

Prior authorization falls into two categories:

- 1. Services or drugs beyond limitations designated in the program. These generally require an override of the designated limits.
- 2. Services or drugs specifically identified as requiring prior authorization.

The physician requests the prior authorization in accordance with the requirements stated on the Drug Criteria and Limits List. If any exception is noted, Medicaid requires the physician to obtain prior authorization in writing in advance of the date of service. Nothing in this chapter would preclude a pharmacy from deciding to act as

intermediary for the request, should they choose to do so. Products which require prior approval are on the Drug Criteria and Limits List with a description of the type of approval required and the criteria. The list may be amended by Medicaid Information Bulletins.

Prior authorization for a pharmaceutical is client specific and product specific. Prior authorization cannot be transferred to another product, to another strength of a previously authorized product, nor to another client.

3 – 1 Fee-for-Service Clients

Prior authorization requirements for pharmacy services apply to ALL fee-for-service clients, defined in Chapter 1 - 6, even though the client may be enrolled in a managed care plan which provides other types of health care services.

The PA requirements and process do not apply to Medicaid patients enrolled in managed care plans which include pharmacy services. Those plans specify which services require authorization and the conditions for authorization.

NOTE: Medicaid staff makes every effort to ensure information provided is accurate. However, obtaining a prior authorization number does not ensure that the client is eligible for Medicaid on the date of service, and neither does it ensure that the client is not enrolled in a managed care plan which includes pharmacy services.

3 – 2 Prior Authorization Process *(Updated 4/1/12)*

1. All Medicaid PA requests for pharmacy must be initiated by sending the most current PA criteria sheet from the Medicaid Pharmacy Services website at <http://health.utah.gov/medicaid/pharmacy>. The criteria sheet must be completely and legibly filled out, and must be accompanied by all requested information. Incomplete and illegible requests will be returned to the prescriber without being processed by Medicaid.

The prescriber furnishes information to justify the need and may submit it either by mail or by Fax. Request for renewing a prior approval must contain justification, along with any additional information required. Do not refer only to the previous prior approval number.

- a. Written Prior Authorization

Mail written requests to:
MEDICAID PRIOR AUTHORIZATION
P.O. BOX 143111
SALT LAKE CITY UT 84114-3111

- b. Fax Number

Prior authorization requests may be faxed to **(855) 828-4992**, attention "Prior Authorizations"

- c. Telephone Prior Authorization

Call Medicaid Information, then follow the telephone menu prompts.

In the Salt Lake City area, call 801-538-6155

Call toll-free in Utah, Arizona, New Mexico, Nevada, Idaho, Wyoming
and Colorado..... 1-800-662-9651

From all other areas 1-801-538-6155

2. If documentation is complete and the request is approved, Medicaid notifies the provider of the prior authorization number. The provider supplies the services to the recipient and bills the Department of Health, Division of Medicaid and Health Financing, through the Point of Sale adjudication system identifying the prior approval number.
3. If documentation is incomplete, the request will be returned by the PA specialist, outlining documentation or actions necessary to get approval. The request will not be processed until documentation is full and complete according to the criteria specified for the PA.
4. If the prior approval request is denied, a letter of denial with an explanation is returned to the requestor, and a copy of the denial and explanation is sent to the recipient. If a prescriber feels that a Medicaid client needs a PA for a drug outside of approved criteria after receiving a denial from a PA specialist, the prescriber may petition to the Drug Utilization Review (DUR) board. This is the first step of the appeal process for all pharmacy prior authorizations. DUR meetings are held on the second Thursday of every month. Petitions to the DUR board must be received one week prior to the monthly meeting. Requests for petitions may be faxed to the PA team at (855) 828-4992. When a petition is denied at the DUR board level, prescribers receive written notification of a denial. If a prescriber wishes to appeal the DUR board denial, he or she can obtain a hearing request form from the Medicaid website at: <http://www.health.utah.gov/medicaid/provhtml/forms.htm>. Follow the instructions on the hearing request form to request a fair hearing.

Any further questioning by provider must be referred to the prior approval specialist who is responsible for the initial action. The signature on the denial or the signature on the letter of information will identify the specialist.

3 - 3 Retroactive Authorization

Retroactive authorization is approval given after a service has been provided. Retroactive authorization may be considered ONLY in the circumstances listed in this chapter.

- A. Retroactive Medicaid Eligibility:
When a client becomes eligible for Medicaid after receiving services which would have required PA, Medicaid may consider a prepayment review, rather than denying reimbursement solely because PA was not obtained. The provider should explain this circumstance with documentation supporting the medical necessity for the service. Even under this condition, the submitted medical record documentation must comply with Medicaid coverage authorization requirements for coverage of the service retroactively. For example, a patient receiving a brand name medication should have medical record information submitted which includes a history of the problem, details of an adverse reaction, allergy to, or inadequate response to generic versions of the drug.
- B. Medications Provided in a Medical Emergency:
Some medications that require PA may be provided in a medical emergency before authorization is obtained from Medicaid. When a medical emergency occurs, and a medication requiring a PA is required, pharmacy providers may provide up to a 72 hour supply of the medication. When contacted, Medicaid will issue an authorization for the 72 hour supply of the medication on the next business day. All subsequent quantities must meet all PA requirements for the medication. It is the responsibility of the medication prescriber to provide the necessary documentation.
- C. Medicaid is responsible for the delay in authorization.

4 COVERAGE LIMITATIONS

Medicaid coverage of pharmaceuticals is subject to the limitations described in this chapter. When the drug requires prior approval, it is included on the drug criteria chart with any age restriction indicated.

4 - 1 Gender and Age of Patient

Drugs must be for the correct gender and/or appropriate age. Examples of gender specific drugs are as follows:

<u>Drug type</u>	<u>Gender</u>
Prenatal	Female
Oral contraceptives	Female
Estroderm	Female

Age limitations on drugs are announced in the Medicaid Information Bulletin. Examples of age restrictions are multiple vitamins, a Medicaid benefit only for children through age five; multiple vitamin supplement (vitamins A, C, and D) without fluoride covered for children up to five years of age only; acne preparations, only for children through the month of the twenty-first birthday.

4 - 2 Maintenance Drugs

Definition: A maintenance medication is any medication or covered pharmacy supply used on an ongoing basis.

Medicaid does not cover any payments for dispensing medications in excess of the practitioner's order. If special circumstances warrant, the pharmacist must provide written documentation on the prescription which must be available for review by the Division of Medicaid and Health Financing.

The pharmacist will receive payment for maintenance medications on the basis of one and only one professional fee for:

1. Each 30 or 31 days supply of tablets, capsules, bulk liquids, or topicals: or
2. Manufacturers' prepackaged powders, topicals, ophthalmic, optics, nasal preparations, and liquids not available in bulk.
3. A trial quantity of less than 30 or 31 days' supply;
4. Glucose test strips. Refer to Chapter 5, Special Drug Provisions, item G.

4 - 3 Controlled Substances *(Updated 4/1/12)*

Controlled drugs are classed in five schedules: Schedules I through V. These drugs are highly regulated. Medicaid does not reimburse for drugs in Schedule I. Federal and State laws govern with regard to the dispensing of all scheduled medications.

Schedule medications (C -III, IV, or V) are not classified as maintenance medications for reimbursement purposes although they may otherwise fulfill maintenance medication criteria. Physicians may prescribe a 30 day supply.

Schedule II and III controlled substance analgesics, and Schedule II long acting analgesics have specific limits as described in the Drug Criteria and Limits List included with this manual (see also Chapter 4-9, Limits on certain drugs).

4 - 4 Prior Approval Policy for Name Brand Drugs *(Updated 4/1/12)*

Brand name drugs require a prior approval (see chapter 3) if an ‘AB’ rated generic alternative is available. The Utah Pharmacy Practice Act mandates use of a generic unless the treating physician demonstrates to the Department of Health a medical necessity for dispensing the non-generic, brand-name legend drug. Prior approval can be obtained by faxing a copy of the information from the patient's medical record that documents that the patient has had an unacceptable adverse drug reaction to the generic version that does not occur with the name brand or has failed to achieve therapeutic efficacy with the generic version. [42 Code of Federal Regulations § 447.331(C) and § 447.331(C)(3)].

If the prescription does not meet coverage requirements, brand name reimbursement is not covered, and Medicaid will retract the entire payment. Telephone orders are not acceptable for brand name drugs unless the pharmacist has received the faxed documentation ruling out use of a generic. The pharmacist can then forward that FAX to the Medicaid prior approval unit. A DAW override is not available for any of the Medicaid programs.

Patient preference does not constitute a medical necessity.

If the brand name is not covered, and the client chooses the brand name drug, the client is responsible for the entire payment. For example, Valium® is not covered by Medicaid because the manufacturer does not participate in the rebate program. If the prescription is for Valium®, and the client chooses Valium over the generic product, the client must pay the entire cost.

4 - 5 Drugs for Nursing Home Patients

With the exception of Schedule II drugs, all medications should be dispensed to nursing home clients with a 30 or 31 days’ supply.

1. Take Home Drugs

Medicaid reimburses the pharmacy for a 30 or 31 days’ supply of drugs for nursing home patients. If a patient is leaving the facility for therapeutic or social reasons, the dispensing pharmacist must provide a labeled take-home container and must place in the container the specific number of units required for the patient while away from the nursing home. These units are to be taken from the month’s supply already provided. No additional units beyond the 30 or 31 days’ supply will be reimbursed.

2. Cycle Filled Prescriptions

Cycle filling of prescriptions is NOT acceptable to Utah Medicaid. A prescription may not be refilled until a minimum of 80 percent of the previous prescription has been used. Refer to Chapter 4 - 7, Early Refills.

The term “cycle” means some action or procedure performed on a routine basis. For example, ‘cycle filled’ prescriptions are those filled on a set schedule, usually every 30 or 31 days, with no reference to the use of the previously dispensed prescription. Typically, the routine is to dispense a month’s supply of medication for the

patient under the physician's orders. At the end of the "cycle," the local or mail order pharmacy delivers to the nursing home or patient's home a new 30 or 31 days' supply of all prescriptions without adjustment for unused units.

Prescriptions furnished to patients residing in extended care facilities (nursing home) MAY NOT be refilled until the previous prescriptions are used, even when an extended period of time occurs. For example, Darvocet is dispensed generically in a quantity of 60, to be taken two daily. If the patient does not actually take the medication as indicated for 45 or 50 days, the prescription may NOT be reordered or refilled.

Unique dispensing methods such as tray changes every two days or every seven days do not justify additional fees. One fee per month is reimbursable even when the product is delivered to a nursing home one tablet at a time.

4 – 6 Compounded Prescriptions

Compounded prescriptions are usually an arrangement between a physician and a specific pharmacy to provide a privately designated combination of drugs as a specific entity. Pharmacists sometimes call compounded prescriptions 'simple dilutions' or simple combinations of two already available ointments. These physician and pharmacy arrangements are not in question.

Claims for compounded prescriptions can be accepted for multiple ingredients. Each ingredient and the appropriate quantity for each must be billed under one prescription number or claim. Up to three dispensing fees will be allowed per compounded prescription. (If the prescription only requires two covered ingredients, only two dispensing fees will be paid. Usual fees are \$3.90 for pharmacies in urban areas, \$4.40 for pharmacies in rural areas, and \$1.00 for a covered over the counter product.) While multiple ingredients will receive multiple fees, single ingredient compounds with non-covered diluents or bases will receive one fee despite the difficulty of some compounded entities. Valid NDC numbers for covered drugs are required for fee payment.

Medicaid will reimburse only for the measured quantity of the covered drugs dispensed, plus the calculated dispensing fees per claim. Incorrect quantities will invalidate the claim. All ingredients must be submitted with the claim, including those that are not covered. The patient will be charged one co-pay for each covered NDC in the compound up to the maximum allowed of five (5). When submitting a compound claim, you are required to submit the following fields for a paid claim:

"Compound Dosage Form Description Code" (field ID #450-EF), which indicates the form the compound will be in its final form. Values are as follows:

01=Capsule	02=Ointment	03=Cream	04=Suppository
05=Powder	06=Emulsion	07=Liquid	10=Tablet
11=Solution	12=Suspension	13=Lotion	14=Shampoo
15=Elixer	16=Syrup	17=Lozenge	18=Enema

"Compound Dispensing Unit Form Indicator" (field ID #451-EG), which indicates how the final product will be measured. Values are as follows: 01=Each 02=Grams 03=Milliliters

"Compound Route of Administration" (field ID #452-EH) indicates how the final product will be used by the client. Values are as follows:

01=Buccal	02=Dental	03=Inhalation	04=Injection
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- | | | | |
|--------------------|----------------|-----------------|------------------------|
| 05=Intraperitoneal | 06=Irrigation | 07=Mouth/Throat | 08=Mucous |
| 09=Nasal | 10=Ophthalmic | 11=Oral | 12=Other/Miscellaneous |
| 13=Otic | 14=Perfusion | 15=Rectal | 16=Sublingual |
| 17=Topical | 18=Transdermal | 19=Translingual | 20=Urethral |
| 21=Vaginal | 22=Enteral | | |

These fields are located in the compound segment. If you are not familiar with where these fields are located, the field ID numbers have been provided for you to discuss with your help desk or software vendor.

*****When you submit a compound claim with non-covered ingredients, you will receive a denial. To process the claim for covered ingredients only, submit the value (8 = Process compound for approved ingredients) in the “Submission Clarification Field”, for reimbursement.**

Following are three examples of reimbursement under the compounded policy:

1. A compounded prescription calls for 10 tablets (with an NDC number) to be crushed and placed in a liquid which is NOT a covered item. Submit a single claim for the tablets with the NDC number, plus your usual fee. Medicaid will reimburse for the tablets and one dispensing fee.
3. The prescription below illustrates a compounded prescription. The pharmacist should submit one claim. Bill Decadron, 60 ml, Benadryl Elix, 60 ml, and simple syrup 60ml which is not covered by Medicaid.

2. A compounded prescription calls for 10 tablets the two legend drugs, plus the total dispensing fee (with an NDC number) to be combined in a liquid which also has an NDC number. Submit one claim, for both NDC’s. Medicaid will reimburse for the tablets and for the liquid, plus two dispensing fees.

Jane Doe	June 9, 1994
Decadron	60 cc
Benadryl Elix	60 cc
Simple syrup	60 cc
Sig 1 Teaspoonful q.i.d.	Signature: J.Doe, MD

4 – 7 Early Refills *(Updated 4/1/12)*

Medicaid provides up to a 30 or 31 days’ supply of a medication to Medicaid clients each month. Once that has been done, the Division’s responsibility has ended. Medicaid pays for a prescription refill ONLY WHEN 80% of the drug is used in accordance with the physician’s orders on the prescription and on the label of the medication. For example, a prescription for a 30 or 31 days’ supply has been 80% used by the 24th day after it was dispensed and it may be refilled at that time.

Certain drugs, such as narcotic analgesic pain medications, are limited to refills only after 30 days and only when 100% of the medication is expected to be used up. A response back to the pharmacy through the online claims processing system will identify those drugs that require 100% of the days supply and quantity to be used before refills are authorized.

A. Early Refills Not Authorized

Medicaid will not pay for a prescription refill under any of the circumstances listed below. Any attempt to refill a prescription through the Point-of-Sale system under these circumstances will be automatically denied.

1. 80% of the drug, in accordance with the physician's orders on the prescription and on the label of the medication, has not been used. For example, a prescription for a 30 or 31 days' supply has not been 80% used until the 24th day after it was dispensed.
2. Medicaid will not pay for a prescription refill when the client does not like the generic version of the prescription, even though the physician writes a new prescription for the name brand. The client may choose to pay for the name brand units or use the generic until the 80% usage or the 24th day is exhausted.
3. Medicaid will not pay for a prescription refill because the client will be out of town for an extended period of time (so-called 'vacation refill.')
4. Medicaid will not authorize an early refill for medications used for palliative treatment or when gross negligence has been displayed by the client.
5. Medicaid will not authorize an early refill for drugs limited by quantity for any 30-day period. Refer to Chapter 4 - 9, Limits on Certain Drugs, and to the Drug Criteria and Limits list included with this manual.

4- 8 Replacement

Medicaid does not pay for replacement of prescriptions which are lost, stolen or otherwise destroyed. Patches that are destroyed during use or fall off will not be replaced by Medicaid. Replacement of prescriptions is the client's responsibility. The early refill policy described in Chapter 4 - 7, Early Refills, does not allow replacement, even though the physician may write a second prescription to cover the loss. A request may be made to allow the early refill, but only in cases of lifesaving necessity.

4 - 9 Limits on Certain Drugs

Drugs identified on the Drug Criteria and Limits List included with this manual are limited by quantity for any 30-day period. These drugs have a cumulative limit and do not qualify for early refills under Chapter 4 - 7, Early Refills. The limits are those approved by the Drug Utilization Review (DUR) Board. Physicians and other prescribers who feel that a patient has specific needs which exceed the limits may appeal to the DUR Board. All medications remain subject to all other requirements of the Utah Medicaid Pharmacy Program, as described in the Utah Medicaid Provider Manual for Pharmacy Services.

4 - 10 Restriction on Package Size or Description

Medicaid reserves the right to restrict coverage on certain package sizes or package descriptions. For example, Medicaid may choose to pay for a drug in a MDV (multi-dose vial) and deny coverage of the same drug packaged in ampules.

4 - 11 Multiple Dispensing Fees Associated with Home Infusion Pharmacy Services

The U.S. Department of Justice (DOJ), as part of a legal process, established a "true AWP" for 437 NDC specific products in 2001. The "true AWP" is close to actual acquisition costs. As a result of the directive from the U.S. Department of Justice (DOJ), effective August 1, 2001, the Division of Medicaid and Health Financing has established multiple dispensing fees associated with select home infusion pharmacy services. To implement this change in dispensing fees, the Division established an Infusion Committee with representatives of the home I.V. infusion specialty pharmacies. The group placed each of the 437 NDCs in one of five categories, according to difficulty of preparation and overhead costs.

Dispensing fee categories are labeled "B", "C", "J", "K", "L", "M". Categories "B" and "C" are for services deemed to be the same as those prescriptions normally filled at a typical retail pharmacy. Category "M" is the most difficult and expensive to prepare.

- Category J includes nebulizer preparations, growth hormone, etc.
- Category K includes simple I.V. antibiotics, anticoagulant treatments, I.V. gamma globulin, etc.
- Category L includes complex antibiotics that require laboratory monitoring and reporting.
- Category M includes chemotherapy I.V.s, pain management, and cardiac ionotropics. For example, chemotherapy requires a separate vertical hood and complete gowning to meet OSHA standards, which adds considerable expense of time and set-up costs.

Categories "J" through "M" will have a new dispensing fee effective August 1, 2001.

Category J	\$ 8.90
Category K	\$ 18.90
Category L	\$ 22.90
Category M	\$ 33.90

The NDCs identified by the DOJ then and in the future will be linked to their counterparts for other manufacturers. Other brands will be reimbursed at the same rate as the DOJ's NDCs. All pharmacies will be reimbursed at the same rate for these NDCs.

5 SPECIAL DRUG PROVISIONS

This section contains information for pharmacies concerning particular drugs or drug classes. Information about limits or Prior Authorization criteria for specific drugs can be found in the Drug Criteria and Limits attachment included with this manual.

5 - 1 DESI Drugs

DESI drugs are combinations of products and single products that, in the Federal Drug Efficacy Study Information (DESI), have not been proven to CMS to be effective for the conditions indicated on the label or in the information packet. DESI drugs are not reimbursable.

DESI drugs are classified by CMS and the manufacturers of combination products into five groups numerically identified beginning with Group 2. The groups are:

- Group 2 Drugs for which Medicaid will receive federal matching funds for the drug program and the indications for product use have been proven effective.
- Group 3 Drugs classified as largely effective for indicated uses and for which federal matching funds are available.
- Group 4 Drugs classified as possibly effective for indicated uses and for which federal matching funds are occasionally (perhaps) available.
- Group 5 Drugs classified as not effective for indicated uses and for which federal matching funds are not available.
- Group 6 New drugs not classified and for which federal matching funds are not available.

Utah Medicaid reimburses drugs in Groups 2 and 3 only. The DESI classification for each product is on the Point of Sale System. Drugs in groups 4, 5, and 6 are considered DESI drugs and are NOT covered by Medicaid. A list of DESI drugs is available from the Medicaid Pharmacy Unit.

5 - 2 Enteral and Parenteral Nutrition and Food Supplements

Enteral nutrition is provided to Medicaid patients by a nasogastric, jejunostomy or gastrostomy tube into the stomach or intestines to supply total nutrition when a non-functioning part of the gastro intestinal tract is present.

Parenteral nutrition is total nutrition administered by intravenous, subcutaneous, or mucosal infusion.

Enteral and parenteral nutrition are reimbursable to pharmacies ONLY through the medical supplies program using five digit codes and billing in the CMS-1500 (08/05) format, electronically or on a paper claim. Refer to the Utah Medicaid Provider Manual for Medical Suppliers.

Some nutrients may have an NDC and remain non-reimbursable in the Pharmacy Program.

Clients requiring total nutrition through surgically attached tubes or semi-permanent nasogastric tubes may have liquid nutritional products that are reimbursable through the Medical Supplies Program.

Clients under the age of five (5) years receiving limited supplementation through the WIC program, may qualify for coverage of supplementation needs above that which WIC provides.

Certain metabolic supplements designed to support in-born errors of metabolism (such as PKU) may be covered, and are billed with an NDC through the point-of-sale system. All supplement coverage requires prior authorization.

5 - 3 Glucose Monitors with Test Strips

Glucose monitors are available to Medicaid clients with no charge to Medicaid. Monitors, manufactured by makers of preferred test strip brands, are provided from the manufacturer to Medicaid clients at no charge. The pharmacists must work with the manufacturer for replacement or reimbursement of monitors. Medicaid need not be contacted.

Blood glucose test strips are a Medicaid covered benefit up to a maximum of 200 strips per month. Prescriptions for quantities in excess of 200 will require an override exception. Test strips are part of the preferred drug list. Prescriptions for non-preferred brands will require a prior authorization. Medicaid reimburses pharmacists AWP plus fee – no percentage deduction.

5 – 4 I. V. Therapy

The purpose of I.V. therapy is to sustain life, reduce or eliminate infections, replace or provide necessary chemicals to maintain electrolyte balance, and provide blood products or chemotherapeutics. I.V. therapy and treatment are only used when the Medicaid client cannot use oral medications. I.V. drugs are available through the Traditional Pharmacy Program. Supplies are billed through the Medical Supplies Program. Home health nursing is available through the Home Health Program.

Care must be taken when requesting reimbursement for I.V. products. Liquid injectables (before and excluding diluents) are billed as milliliters. Dry powder, by lyophilized vials, are billed as “each,” or a unit of one. Diluents covered by Medicaid are billed separately by NDC and quantity such as 50 ml., 100 ml., 1000 ml.

Federal rulings have disqualified Heparin flushes for coverage under the Medicaid pharmacy program. Any product used to “flush” or maintain an IV line is not considered a pharmaceutical and is not covered.

5 - 5 Niche Drugs

Products mailed directly to a patient from the manufacturer using a single designated distributor are not covered by Medicaid. Manufacturers are increasingly shipping products, developed to target specific diseases, directly to patients via a Pharmacy Benefit Management service.

Medicaid will not enter into agreements or utilize distribution programs that violate patient confidentiality or prohibit free trade of a product. When products are available through usual and customary channels to all pharmacies, the products will become Medicaid benefits.

5 – 6 Blood Factors

Medicaid restricts hemophilia blood factors to a single provider. The purpose is to provide a uniform hemophilia case management support program to the patient and patient’s physician and to achieve economies in the purchase of blood factor through a sole source contract. Medicaid will reimburse only the sole source provider for hemophilia case management, blood factors VII, VIII and IX. No other provider will be paid for blood factors VII, VIII or IX. Medicaid clients who choose not to participate in the Medicaid Hemophilia program must make their own arrangements for procurement and payment of the blood factor.

The contract affects the procurement and management of the prescribed blood factor. The patient’s physician continues to be responsible to develop a plan of care and to prescribe the blood factor. The contract with the sole source provider specifies the provider must work closely with the patient’s Primary Care Provider physician or managed care plan.

Managed care plans which contract with Medicaid continue to be responsible for hemophilia-related services such as physical therapy, lab work, unrelated nursing care, and physician services.

As of October 2000, the sole source provider is University Hospital Home Infusion Services. Please direct questions concerning hemophilia case management and blood factors VII, VIII and IX to this provider: (801) 213-9600.

5 - 7 Immunization Reimbursement Methodology

Medicaid utilizes Centers for Disease Control (CDC) pricing information and Estimated Acquisition Cost (EAC) in determining the reimbursement rates for immunizations paid by fee-for-service Medicaid. Medicaid will continue to use lesser logic and reimburse the lower of CDC and EAC.

CDC pricing information can be found at <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>.

5-8 Vitamins

Vitamins covered by Utah Medicaid include prenatal vitamins with folic acid for pregnant women, multiple vitamins with or without fluoride for children through age five, and fluoride supplements. These vitamins are covered for up to a one hundred days supply per dispensing.

Prenatal vitamins are only covered for pregnant women. Prenatal vitamins are not covered post-delivery. As part of the pharmacy counseling requirement, the pharmacist must establish the client's due date (month and year) and write it on the prescription. The due date notation will suffice for audit purposes. Pharmacies must indicate that the client is pregnant by using the pregnancy indicator value "2" in the appropriate NCPDP field. Claims for prenatal vitamins will not be covered unless the pharmacy indicates that the client is pregnant.

5-9 Oral Contraceptives

Utah Medicaid will pay for up to three months of birth control per dispensing.

5-10 Pharmacist-Administered Vaccines

Medicaid covers the seasonal influenza vaccine, Zostavax, and Pneumovax for Traditional Medicaid clients as a pharmacy benefit. These vaccines will be reimbursed at the rate of EAC plus a "J" dispensing fee of \$8.90.

5-11 Drugs Requiring ICD.9 Codes

All atypical antipsychotics require a select diagnosis code using the ICD.9 format. Covered diagnoses are determined according to the three following age groups: ages 0 through 6; ages 7 through 19; ages >19. Attachments to Section 2 of the Medicaid Pharmacy Provider Manual show covered ICD.9 codes for each age group respectively.

All stimulants for the treatment of ADD/ADHD in clients under the age of 19 require the appropriate ICD.9 diagnosis code for payment.

Cumulative limits on long-acting narcotic analgesics and short-acting single entity narcotic analgesics are waived for the treatment of cancer-related pain. Additionally, Fentanyl 100mcg patches, fentanyl lozenges, and fentanyl buccal tablets are covered only for cancer-related pain. The prescriber must provide an appropriate ICD.9 diagnosis code for cancer on prescriptions for these drugs.

It is the prescriber's responsibility to provide the correct ICD.9 code on each prescription for an atypical antipsychotic, ADD/ADHD medication, or narcotic pain medication for cancer pain. The ICD.9 code may be hand-

written by the prescriber on the prescription or computer generated by prescribing software. Pharmacy providers may also obtain ICD.9 codes verbally from prescribers, and note the date, time, and name of the physician's representative providing the ICD.9 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 ICD.9 code. The pharmacist must enter the ICD.9 code into the appropriate diagnoses field when processing a claim.

Additionally, Bupropion products and Cymbalta require an ICD.9 code classification to be entered by the pharmacy when billed through the Pharmacy POS System.

- Bupropion must be classified as smoking cessation (305.1) or depressive disorders (311).
- Cymbalta prescriptions must be classified as neuralgias (729.2) or depressive disorders (311).

As part of normally required counseling, pharmacy staff may ask a patient what condition is being treated and categorize bupropion and Cymbalta prescriptions accordingly. For these two drug products, the diagnosis **does not** need to be written on the prescription by the prescriber.

6 REIMBURSEMENT POLICIES *(Updated 4/1/12)*

6 - 1 Point-of-Sale System

Effective April 1, 2000, Medicaid requires all pharmacy claims to be submitted electronically through the Point of Sale system.

The Point of Sale (POS) system provides pharmacists with the capability to submit pharmacy claims electronically. It enables pharmacies to immediately determine Medicaid client eligibility, verify drug coverage, and have "real time" claim processing. Federal law has mandated the use of NCPDP D.0 effective January 1, 2012. NCPDP is the National Council for Prescription Drug Programs and is the national standards organization for prescription claim formats. All pharmacies routinely billing Utah Medicaid must use NCPDP D.0 beginning January 1, 2012, when billing Medicaid through Point-of-Sale.

6 - 2 Prospective Drug Utilization Review (PRODUR)

PRODUR, Prospective Drug Utilization Review Program, is an adjunct to the Point of Sale (POS) system used for pharmacy claims. It is a system to monitor the client's complete Medicaid drug history, including any pharmacy or physician. It identifies on the computer screen, as the prescription is being filled, any potential adverse drug events (ADE) of severity level 1, drug duplicates as well as therapeutic class drug duplicates. PRODUR contains modules to review drug interactions and responds with a message to the pharmacist. Modules include: Minimum - Maximum Dose, Dose range (cumulative dose), Duplication, Drug - Drug Interaction, Drug - Disease Interaction, Minimum/Maximum Pediatric Daily Dose, Minimum/Maximum Geriatric Daily Dose and Side Effects Module. Criteria for the Side Effects Module are listed in this chapter.

If you would like more information on PRODUR, please contact Medicaid Information.

6 - 3 Maximums and Minimums

Utah Medicaid has implemented the Maximums and Minimums fields with acceptable quantities. Drugs available in certain quantities are covered in that quantity and multiples of those quantities. For example, an injectable product only available as a 2.5 ml. vial will have a minimum of 2.5 and a maximum of a multiple of 2.5. Products such as antibiotics in 75 ml, 100 ml, 150 ml., or 200 ml are covered only in those quantity and multiples of those quantities. Other quantities, such as 35 ml for a 75 ml product, or 430 for the product, are not covered.

6 - 4 Decimal Quantities

Pharmacies must bill using metric decimal quantities to the second decimal when entering the units dispensed. Use metric decimal quantity field (Field 442-E7). This affects ophthalmic preparations, otic preparations, inhaler and selected injectable preparations. For example: Vanceril® inhaler (NDC 00085073604) must be expressed as 16.80 units or an even multiple of 16.80 units. (Examples: $2 \times 6.80 = 33.60$ units; $3 \times 16.80 = 50.40$ units).

Pharmacies may not round up the decimal quantity to the next whole number. If the decimal quantity is rounded up to the next whole number, the claim will be rejected. When the Point of Sale program began in 1994, each pharmacy that signed on agreed to accept NCPDP's standardized electronic claims format. As of July 1, 1998, the standard changed to require decimal quantities to the second decimal.

6 - 5 Counseling

Effective use of the Point-of-Sale and PRODUR systems is the basis for patient counseling.

Patient counseling is mandated by OBRA 1990, OBRA 1993, and Utah Pharmacy Practice Act. Counseling the client and interfacing with the physician are integral parts of the pharmacy function of dispensing. Audits of pharmacies are performed regularly in conjunction with the Department of Professional Licensing (DOPL).

Counseling is included as part of the dispensing fee, and the pharmacist must instigate dialog by offering to counsel the client. Mail order pharmacies which do not offer counseling up-front are subject to a lesser fee. Providing the package insert is not considered counseling.

6 - 6 Rebate Program

OBRA 1990 mandates that all drug manufacturers whose products are dispensed to Medicaid clients provide a discount or rebate back to the individual states. Medicaid is the single largest user of drugs nationwide and, as such, is entitled to a discount such as hospitals and other organizations receive.

Each quarter of a calendar year, Medicaid produces a list of drugs by National Drug Code (NDC). The list includes the number of units of each NDC which the state has paid to all pharmacies. The list is sent to each manufacturer. The manufacturer applies its rebate criteria, multiplies the number of units by the rebate per unit (RPU) and pays Medicaid that rebate amount.

To ensure accuracy in the drug list, pharmacies shall ensure claims submitted conform to the following reporting requirements:

1. All products must be billed with correct decimals for any fractions dispensed. Here are some examples of correct decimals for fractional quantities: 2.5ml; 15 gram tubes; 12.5 for 1/8 oz. ointments; 15.7ml inhalers.
2. All medications must be billed in accurate quantities, particularly injectable medications. Liquid vials should be billed by ml. For example, a 10 ml. vial equals 10 units, a 20 ml. vial equals 20 units. Dry powder vials are

billed as 'each'. Each vial equals quantity one. The diluent used to liquefy a dry powder is billed separately by NDC and units (ml.) of liquid.

Some items are limited by computer edits to allow only a specified minimum or an even multiple of that minimum, i.e. 3 x 2.5ml.

3. Ensure that your computer entries for quantities are accurate.

Pharmacies shall make sure that computer 'stutter' does not result in inaccurate quantities, such as 60,000 instead of 60.

4. Only the NDC of the product dispensed is billed. The NDC for the generic brand is billed when a generic brand is dispensed. Do NOT bill Medicaid for a name brand NDC when a generic brand was dispensed. Common billing errors include billing for Keflex, Mellaril, Stelazine, or Depakene when generics were dispensed.
5. The pharmacist or technician shall write the name of the manufacturer on the prescription when actually transferring a product from a stock container into a vial for a specific patient. To ensure accuracy, Medicaid requires the name of the manufacturer to be written on the prescription by the pharmacist or technician who is actually holding the product dispensed. A manufacturer is permitted under OBRA 90 to request verification of the NDC billed to Medicaid or requesting invoices to substantiate purchases.

Manufacturers gather data such as names, addresses, reimbursement and specific errors made by pharmacies when dispensing. Manufacturers assume it is not likely that pharmacies repeatedly accept generic reimbursement while billing innovator NDCs. Therefore, when a manufacturer denies the rebate and names pharmacies which billed for name brand NDCs but accepted generic level reimbursement, both the manufacturer and Medicaid will request a copy of the prescription to verify the manufacturer written on the prescription and a copy of the pharmacy purchase invoice. Suitable penalties will be applied when discrepancies exist between the manufacturer identified and the NDC billed.

Rebates may affect Medicaid coverage. In addition to primary rebates, Utah Medicaid negotiates for supplemental rebates for products on the preferred drug list. Utah Medicaid reserves the right granted in Utah Code 58-17b-606(5) to cover any medication preferentially, whether or not on the preferred drug list, based on the final cost to Medicaid after all rebates are considered. This means, for example, that Medicaid may cover some brand name drugs preferentially over any generics that may be available, even though the brand may cost the provider pharmacy more because in these cases, the final cost to Medicaid is less for the brand. Provider pharmacies should refer to the online coverage response for information regarding any product.

6 - 7 J-Code Billing

In order to comply with the provisions of the Deficit Reductions Act (DRA) of 2006, section 6002, billings for medications administered in the physician's office must include the National Drug Code (NDC) from the container from which the medication is obtained, and the number of units administered in addition to the "J" Code normally used. Billings for all drugs administered in the physician's office without the NDC information will be denied for payment beginning with the reporting deadline of January 1, 2007, specified in the DRA for single source drugs.

The following information must be provided on a CMS-1500 (08/05) Claim Form when billing for office administered drugs:

- A. NDC - Box 24D, shaded area

- B. Drug Unit Price - Box 24F, shaded area
- C. Basis of Measurement Qualifier and Units - Box 24G, shaded area. Use the following qualifiers:
- ME - for milligrams
 - ML - for milliliters
 - GR - for grams
 - UN - for units

Outpatient hospital departments that are billing individually for drugs must also provide the NDC when billing Medicaid on the UB-04 claim form.

When billing a procedure that requires a NDC code (done under contract with a payer), enter the NDC on the 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 CMS-1500 (08/05) or 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, UN)

2410 CTP04= Number of units (place the number of units immediately after the units qualifier)

2410 CTP03= Cost or Unit Price

Medicaid currently edits if the NDC submitted is valid. The NDC must be entered with 11 digits in a 5-4-2 digit format. The first five digits of the NDC are the manufacturer's labeler code, the middle four digits are the product code, and the last two digits are the package size. If you are given an NDC that is less than 11 digits, add the missing digits as follows:

- For a 4-4-2 digit number, add a 0 to the beginning.
- For a 5-3-2 digit number, add a 0 as the sixth digit.
- For a 5-4-1 digit number, add a 0 as the tenth digit.

7 INDIAN HEALTH PROGRAM

The Indian Health Program services can be provided by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

Services provided by facilities of the Indian Health Service, which include at the option of a tribe or tribal organization, services by tribal 638 facilities funded by Title I or Title III of the Indian Self-Determination and Education Assistance Act (P.L. 93-638), are reimbursed at the rate negotiated between CMS and the IHS and published in the Federal Register. The reimbursement is called an All Inclusive Rate (AIR). The AIR is established by CMS and IHS based upon a review of yearly cost reports prepared by IHS's contractor. Upon completion of the review, IHS submits the agreed upon rate to the Office of Management and Budget (OMB) for approval. Upon approval by OMB, IHS publishes the approved rate in the Federal Register.

7 - 1 Indian Health Service and Tribal 638 Programs Coverage Policy

- A. Traditional Medicaid: IHS and Tribal 638 Programs are subject to the policy and procedures described in this manual.
- B. Non-Traditional Medicaid: IHS and Tribal 638 Programs are subject to the policy and procedures described in this manual and the Non-Traditional Medicaid provider manual.
- C. Primary Care Network (PCN): IHS and Tribal 638 Programs are subject to the policy and procedures described in this manual and the Primary Care Network (PCN) provider manual.

7 - 2 All Inclusive Rate

The Indian Health Service publishes the IHS reimbursement rates in the Federal Register, under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a) and 249(b) and section 601 of the Indian Health Care Improvement Act (25 U.S.C. 1601). Utah IHS/tribal facilities are reimbursed in accordance with the most current Federal Register Notice, published by IHS and approved by CMS.

7 - 3 Negotiated Rate

The reimbursement rate for pharmacy is a negotiated amount between the state and the Utah Tribes. The negotiated rate is the All Inclusive Rate (AIR).

7 - 4 Utah IHS Pharmacy Reimbursement

- A. Traditional and Non-Traditional Medicaid: Reimbursement for Pharmacy services is limited to one AIR per person, per prescriber, per encounter, per day (see instructions for billing a second medically necessary encounter).
- B. Primary Care Network (PCN): Reimbursement for Pharmacy services is limited to four AIRs per person, per month. Four prescriptions by one prescriber (or up to four prescribers) on a single day would be reimbursed as four AIRs. PCN clients are eligible for four prescriptions per month.

7 - 5 IHS Pharmacy Encounter

- A. Traditional and Non-Traditional Medicaid: An IHS pharmacy encounter means a prescriber's prescription(s) fill/refill at an IHS pharmacy. Multiple prescriptions (by prescriber) that are filled/refilled on the same day and at a single IHS pharmacy constitute a single encounter except when the recipient, after the first visit, suffers an illness or injury requiring additional diagnosis or treatment (see instructions for billing a second medically necessary encounter).
- B. Primary Care Network (PCN): An IHS pharmacy encounter means a prescription fill/refill at an IHS pharmacy. Multiple prescriptions that are filled/refilled on the same day and at a single IHS pharmacy constitutes multiple encounters. PCN clients are eligible for four prescriptions per month.

7 - 6 Instructions for Billing a Second Medically Necessary Encounter

- A. Traditional and Non-Traditional Medicaid: With the exception of transportation services, only one encounter is reimbursed within the same service category, for services that take place on the same day and at a single IHS outpatient location, except when the recipient after the first visit suffers an illness or injury requiring additional diagnosis or treatment. When such a second medically necessary encounter occurs, and additional pharmacy services are requested, the IHS pharmacy must contact Utah Medicaid with documentation explaining the circumstances which supports the request for payment of the second encounter.
- B. Primary Care Network (PCN): Prescriptions for PCN clients are filled/refilled regardless of the date of service or the prescriber; however, PCN clients are limited to four prescriptions per month.

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