

10-004.05C Definition of Clinical Trials: For services not subject to FDA approval, the following definitions apply:

Phase I: Initial introduction of an investigational service into humans

Phase II: Controlled clinical studies conducted to evaluate the effectiveness of the service for a particular indication or medical condition of the patient; these studies are also designed to determine the short-term side effects and risks associated with the new service

Phase III: Clinical studies to further evaluate the effectiveness and safety of a service that is needed to evaluate the overall risk/benefit and to provide an adequate basis for determining patient selection criteria for the service as the recommended standard of care. These studies usually compare the new service to the current recommended standard of care.

10-004.06 Autopsies: Autopsies are a non-covered service under NMAP.

10-004.07 Custodial or Respite Care: NMAP does not cover hospital services that are custodial or respite care.

10-004.08 Facility Based Physician Clinics: Physician Clinic services provided in a hospital location or a facility under the hospital's licensure are considered content of the physician service, not outpatient hospital services. Physician clinic services are defined as the professional activity, any drugs and supplies used during that professional encounter, and any other billable service provided in the physician clinic area.

1. Nebraska Medicaid does not recognize facility/hospital based non-emergency physician clinics for billing, reimbursement or cost reporting purposes except for itinerant physicians as defined in 471 NAC 18-004.41/10-005.21.
2. Services and supplies incident to a physician's professional service provided during a specific encounter are covered and reimbursed as physician clinic services if the service or supply is:
 - a. Of the type commonly furnished in a physician's office;
 - b. Furnished as an incidental, although integral, part of the physician professional services; and
 - c. Furnished under the direct personal supervision of the physician.
3. The Physician's clinic services ~~shall~~must be billed on Form CMS-1500 or the standard electronic Health Care Claim: Professional transaction (ASC X12N 837).

[10-004.09 Tobacco Cessation Services: Tobacco cessation services are not covered as a hospital service. Please see 471 NAC 16-000, Pharmacy Services and 471 NAC 18-000, Physicians' Services for coverage information.](#)

CHAPTER 16-000 PHARMACY SERVICES

16-001 Standards for Participation: A provider of pharmacy services must be a licensed pharmacy, licensed pharmacist, or a dispensing physician. To participate in the Nebraska Medical Assistance Program (NMAP), the provider ~~shall~~ must fully meet the standards established by the Department of Health and Human Services ~~Finance and Support~~ and any applicable state and federal laws or regulations governing the provision of the service. Providers ~~shall~~ must meet all the Department's pharmacy regulations contained in this chapter.

The pharmacy provider ~~shall~~ must complete and sign Form MC-19, "Medical Assistance Provider Agreement," (see 471-000-90) and submit it to the Department to be approved for provider enrollment. Approval may be denied or withdrawn at the discretion of the Director.

16-001.01 Tobacco Cessation Counseling: As a condition of participation as a Tobacco Cessation Counselor, the provider must:

1. Be a licensed pharmacist;
2. Complete a Department-approved tobacco cessation counselor training;
3. Maintain current certification as a Tobacco Cessation counselor as required by the Department;
4. Complete and sign a new provider agreement (Form MC-19), indicating the employing pharmacy as the "pay to" provider, and submit a copy of the Department-required certification as part of the provider agreement completion process, or upon request by the Department;
5. Provide Tobacco Cessation counseling which is separate and distinct from the prospective drug utilization review that is required in 471 NAC 16-001.02 and is not related to the dispensing of any drug product; and
6. Provide feedback to the physician/midlevel practitioner who ordered the services.

16-001.012 Drug Utilization Review: As a condition of participation, the provider is required to ~~;~~

1. Provide prospective drug utilization review before dispensing each prescription. This ~~shall~~ must include screening for ~~;~~
 - a. Therapeutic duplication;
 - b. Drug disease contraindications;
 - c. Drug interactions;
 - d. Incorrect dosage or duration;
 - e. Drug allergies; and
 - f. Clinical abuse/misuse;
2. Provide patient counseling on all matters which, in the provider's professional judgment, are deemed significant, including ~~;~~
 - a. Name/description of the medication;
 - b. Route, dosage form, duration of therapy;
 - c. Directions for use;
 - d. Adverse reactions, contraindications;
 - e. Storage; and
 - f. Refill information; and

3. Make a reasonable effort to obtain, record, and maintain adequate patient profiles which, in the provider's professional judgment, are deemed significant. This may include -:
 - a. Name, address, phone number, age, and gender;
 - b. Individual history (i.e., diseases, allergies, drug reactions)
 - c. Comprehensive listing of medications; and
 - d. Relevant comments.

16-002 Covered Services: NMAP covers outpatient drugs in accordance with the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Public Law 101-508) including ~~;~~

1. Legend drugs;
2. Compounded prescriptions; and
3. Over-the-counter (OTC) drugs indicated as covered on the Nebraska Point of Purchase (NE-POP) System or LISTED ~~on the Department's Drug Name/License Number Listing microfiche or~~ on the Department's website.

See 471 NAC 16-003, Non-Covered Services; 471 NAC 16-004.01A, Products Requiring Prior Approval; coverage as indicated on NE-POP System; ~~and the Department's Drug Name/License Number Listing microfiche website~~ for exceptions to the above.

16-002.01 Compounded Prescriptions: A compounded prescription is a mixture of ingredients which the provider prepares in the pharmacy.

Any mixture of drugs which results in a commercially available OTC preparation is not considered a compounded prescription, for example, dilute HCL, MOM with cascara, OTC hydrocortisone preparations. (See the NE-POP System user's manual for billing instructions.)

16-002.02 Over-the-Counter (OTC) Drugs: NMAP covers only OTC drugs indicated as covered on the NE-POP System or LISTED ~~on the Department's Drug Name/License Number Listing microfiche or~~ on the Department's website. OTC drugs must be prescribed by a licensed practitioner.

16-002.03 HEALTH CHECK (EPSDT) Treatment Services: Services not covered under the Nebraska Medical Assistance Program (NMAP) but defined in Section 1905(a) of the Social Security Act must meet the conditions of items 1 through 6 listed in the definition of "Treatment Services" in 471 NAC 33-001.03. These services must be prior authorized by the ~~Medicaid~~ Division ~~of Medicaid and Long-Term Care~~ of the Department of Health and Human Services ~~Finance and Support~~.

16-002.04 Tobacco Cessation Counseling: ~~In addition to a physician/mid-level practitioner, only a licensed pharmacist, meeting Department requirements as a Tobacco Cessation Counselor, may provide tobacco cessation counseling.~~

16-003 Non-Covered Services: Payment by NMAP will not be approved for:

1. More than a three-month supply of birth control tablets. More than a three-month supply of oral medication. More than 100 tablets or capsules of medication taken once daily. More than a three-month supply of any other medication, except injectable medications. More than a one-month supply of any injectable medication, except insulin and those injectable drugs with a duration of greater than one month from one dose (e.g., Lupron Depot 4 month, Depo-Provera Contraceptive 150 mg.).
2. Experimental drugs or non-FDA approved drugs;
3. Drugs or items when the prescribed use is not for a medically accepted indication;
4. Drugs or items prescribed or recommended for weight control and/or appetite suppression (see 471 NAC 16-004.03);
5. Liquors (any alcoholic beverage);
6. D.E.S.I. drugs and all identical, related, or similar drugs;
7. Personal care items (examples: non-medical mouthwashes, deodorants, talcum powders, bath powders, soaps, dentifrices, eye washes, and contact solutions);
8. Medical supplies and certain drugs for nursing facility and intermediate care facility for the mentally retarded (ICF/MR) patients (see 471 NAC 7-000 and 16-004.04);
9. Over-the-counter (OTC) drugs not listed on the Department's [Drug Name/License Number Listing microfiche website](#);
10. Drugs or items used for cosmetic purposes or hair growth;
11. Baby foods or metabolic agents (Lofenalac, etc.) normally supplied by Nebraska Department of Health and Human Services (see 471 NAC 16-002.03 for exceptions);
12. Drugs distributed or manufactured by certain drug manufacturers or labelers that have not agreed to participate in the drug rebate program;
- ~~13. Smoking cessation products;~~
- ~~4413.~~ Products used to promote fertility;
- ~~4514.~~ Medications dispensed as partial month fills for nursing facility or group home residents when dispensed by more than one pharmacy;
- ~~4615.~~ Drugs, items or products of manufacturers/labelers that are identifiable as non-covered on the Ne-POP system, ~~or on the Department's Drug Name/License Number listing,~~ or on the Department's website;
- ~~4716.~~ Drugs, classes of drugs or therapeutic categories of drugs that are Medicare Part D Drugs and Medicare Part D Covered supplies or equipment, for all persons eligible for benefits under Medicare Part D, whether or not such persons are enrolled into a Medicare Part D Plan (see 471 NAC 3-004 for definitions of Medicare Part D Drugs, Medicare Part D Covered supplies and equipment, Medicare Part D and Medicare Part D plan); and
- ~~4817.~~ Drugs or classes of drugs approved by the Federal Food and Drug Administration for treatment of sexual or erectile dysfunction, or drugs or classes of drugs that are being used for the treatment of sexual or erectile dysfunction. Drugs or classes of drugs that are approved by the Federal Food and Drug Administration for treatment of sexual or erectile dysfunction and for conditions other than treatment of sexual or erectile dysfunction, and are prescribed for those other conditions may be covered, but NMAP may require prior authorization. (See 471 NAC 16-004).

16-004.01A Products Requiring Prior Approval: The following products require prior approval:

1. Sunscreens (Example: Presun 29, Solbar-50);
2. Certain modified versions, double-strength entities, or products considered by the Department to be equivalent to drug products contained on the state or federal upper limit listings (Example: Libritabs, Keftabs);
3. Human Growth Hormone;
4. Erythropoietin (Example: Epogen, Procrit);
5. Drugs or supplies intended for convenience use (Example: Refresh Ophthalmic 0.3 ml. and Novalin penfil insulin);
6. Drugs used for prevention of infection with respiratory syncytial virus (e.g., respiratory syncytial virus immune globulin, palivizumab); and
7. Certain drugs or classes of drugs used for gastrointestinal disorders, including but not limited to hyperacidity, gastroesophageal reflux disease, ulcers or dyspepsia (examples: omeprazole, famotidine);
8. Certain drugs or classes of drugs used for relief of pain, discomfort associated with musculoskeletal conditions, inflammation or fever (examples: butorphanol, carisoprodol, tramadol);
9. Certain drugs or classes of drugs used for relief of cough and/or symptoms of the common cold, influenza or allergic conditions (examples: loratadine, zanamivir, oseltamivir);
10. Certain drugs or classes of drugs that are used for non-covered services or indications (see 471 NAC 16-003 Non-Covered Services) and for covered services or indications (examples: orlistat, sildenafil);
11. Certain drugs or classes of drugs on the state maximum allowable cost or federal upper limit listings; ~~and~~
12. Certain drugs or classes of drugs upon initial availability or marketing or when Nebraska Medicaid coverage begins; and
13. Certain drugs or classes of drugs that are used for tobacco cessation.

Identifiable products requiring approval prior to payment are designated as such on the NE-POP System ~~or the Department's Drug Name/License Number Listing microfiche~~ or on the Department's website.

16-004.06D Maintenance Drugs: The Department requires that any other maintenance drug or any drug used in a chronic manner be prescribed and dispensed in a minimum of a one-month supply.

Note: Providers ~~shall~~ must not reduce prescriptions which are written for quantities larger than a month's supply to a month's supply. The Department considers prescription splitting to be fraudulent.

16-004.06E Tobacco Cessation: Medicaid covers tobacco cessation services as practitioner and pharmacy services under the following conditions:

1. Up to two tobacco cessation sessions may be covered in a 12-month period. A session is defined as medical encounters and drug products as listed in items 3 and 4 below. Client access to the Nebraska Tobacco Free Quitline will be unlimited.
2. Nebraska Tobacco Free Quitline: Clients must be enrolled in and active with the Nebraska Tobacco Free Quitline. Referral to the Quitline may be made by a medical professional (physician/mid-level practitioner) or a self referral.
3. Practitioner Office Visits:
 - a. Clients must see their medical care provider (physician/mid-level practitioner) for evaluation particularly for any contraindications for drug products and to obtain prescription(s) if tobacco cessation products are needed.
 - b. (1) In addition to the evaluation under item 3a, a total of four tobacco cessation counseling visits with a medical care provider or tobacco cessation counselor (see 471 NAC 16-002.04) are covered. This may be a combination of intermediate or intensive tobacco cessation counseling visits.
(2) Tobacco cessation counseling provided by a Tobacco Cessation counselor must be ordered by the physician/mid-level practitioner.
4. Tobacco cessation products are covered by Medicaid as a pharmacy service (see 471 NAC 16-000) for those clients 18 years of age or older who require that particular assistance.
 - a. Coverage of drug products used for tobacco cessation is limited to a maximum 90 days supply in one tobacco cessation session. The coverage period is limited to 90 consecutive calendar days, beginning with the date the first prescription for the products is dispensed.
 - b. Tobacco cessation products will only be covered when clients are currently enrolled with and actively participating in the Nebraska Tobacco Free Quitline. Disenrollment or lack of active participation in the Nebraska Tobacco Free Quitline will result in discontinuation of Medicaid coverage of drug products.

16-004.06EF Exceptions to Quantity Limitations: The Department allows the following exceptions to the quantity limitations of this subsection only for those clients that are receiving their medications by/through a non-unit-dose system, except where noted otherwise:

1. When the prescribing physician first introduces a maintenance drug to a patient's course of therapy, the physician may prescribe as his judgment dictates. Pharmacists ~~shall~~ must indicate that this is the initial filling of the medication when filing the drug claim. Any subsequent dispensing of this maintenance drug must be prescribed and dispensed in at least a month's supply.
2. When the prescribing physician's professional judgment indicates that these quantities of medication are not in the patient's best medical interest, the physician may prescribe as his/her judgment directs. This includes limitations for lock-in clients. The pharmacist ~~shall~~ must maintain documentation that an exception is being made to the Department's requirements.

7. Personal care items (examples: non-medical mouthwashes, deodorants, talcum powders, bath powders, soaps, dentifrices, eye washes, and contact solutions);
8. Medical supplies and certain drugs for nursing facility and intermediate care facility for the mentally retarded (ICF/MR) patients;
9. Over-the-counter (OTC) drugs not listed on the Department's ~~Drug Name/License Number Listing microfiche~~ or web site;
10. Drugs or items used for cosmetic purposes or hair growth;
11. Baby foods or metabolic agents (Lofenalac, etc.) normally supplied by the Nebraska Department of Health and Human Services (see 471 NAC 16-002.03 for exceptions);
12. Drugs distributed or manufactured by certain drug manufacturers or labelers that have not agreed to participate in the drug rebate program;
- ~~13. Smoking cessation products;~~
- ~~1413.~~ Products used to promote fertility;
- ~~1514.~~ Medications dispensed as partial month fills for nursing facility or group home residents when dispensed by more than one pharmacy;
- ~~1615.~~ Drugs, items or products of manufacturers/labelers that are identifiable as non-covered on the Ne-POP system, ~~or on the Department's Drug Name/License Number listing,~~ or on the Department's website;
- ~~1716.~~ Drugs, classes of drugs or therapeutic categories of drugs that are Medicare Part D Drugs and Medicare Part D Covered supplies or equipment, for all persons eligible for benefits under Medicare Part D, whether or not such persons are enrolled into a Medicare Part D Plan (see 471 NAC 3-004 for definitions of Medicare Part D Drugs, Medicare Part D Covered supplies and equipment, Medicare Part D and Medicare Part D plan); and
- ~~1817.~~ Drugs or classes of drugs approved by the Federal Food and Drug Administration for treatment of sexual or erectile dysfunction, or drugs or classes of drugs that are being used for the treatment of sexual or erectile dysfunction. Drugs or classes of drugs that are approved by the Federal Food and Drug Administration for treatment of sexual or erectile dysfunction and for conditions other than treatment of sexual or erectile dysfunction, and are prescribed for those other conditions may be covered, but NMAP may require prior authorization. (See 471 NAC 16-004).

18-004.25C Prior Authorization: The Department requires that approval be granted prior to payment for certain drugs or items. Physicians wishing to prescribe these drugs or pharmacists ~~shall~~ **must** fully obtain prior authorization, by submitting the request either by standard electronic transaction or by phone or mail from ~~;~~:

The Pharmacy Consultant (or designee)
Nebraska Department of Health and Human Services ~~Finance and Support~~
~~Medicaid~~ Division of Medicaid and Long-Term Care
P. O. Box 95026
301 Centennial Mall South, 5th Floor
Lincoln, NE 68509
(402) 471-9379
FAX: (402) 471-9092

The Department (and/or its designee) will respond to any request for prior authorization within 24 hours of receipt of the request.

18-004.25C1 Products Requiring Prior Approval: The following products require prior approval:

1. Sunscreens (Examples: Presun 29, Solbar-50);
2. Certain modified versions, combinations, double-strength entities, or products considered by the Department to be equivalent to drug products contained on the state maximum allowable cost or federal upper limit listings (Examples: Libritabs, Keftabs);
3. Human Growth Hormone;
4. Erythropoietin (Examples: Epogen, Procrit)
5. Drugs or supplies intended for convenience use (Example: Refresh Ophthalmic 0.3 ml; Novolin penfil insulin);
6. Respiratory syncytial virus prophylactic therapies;
7. Certain drugs or classes of drugs used for gastrointestinal disorders, including but not limited to hyperacidity, gastroesophageal reflux disease, ulcers or dyspepsia (examples: omeprazole, famotidine);
8. Certain drugs or classes of drugs used for relief of pain, discomfort associated with musculoskeletal conditions, inflammation or fever (examples: butorphanol, carisoprodol, tramadol);
9. Certain drugs or classes of drugs used for relief of cough and/or symptoms of the common cold, influenza or allergic conditions (examples: loratadine, zanamivir, oseltamivir);
10. Certain drugs or classes of drugs that are used for non-covered services or indications (see 471 NAC 16-003 Non-Covered Services) and for covered services or indications (examples: orlistat, sildenafil);
11. Certain drugs or classes of drugs on the state maximum allowable cost or federal upper limit listings; ~~and~~
12. Certain drugs or classes of drugs upon initial availability or marketing or when Nebraska Medicaid coverage begins; ~~and~~
13. Certain drugs or classes of drugs that are used for tobacco cessation.

Identifiable products requiring approval prior to payment are designated as such on the NE-POP System or the Department's Drug Name/License Listing microfiche or web site.

18-004.25D Physician Certification of FUL/SMAC Drugs: If the prescribing physician requires that a brand name product of a federal upper limit (FUL) or a state maximum allowable cost (SMAC) designated drug is medically necessary, the Department requires the physician to sign and date Form MC-6, "Physician Certification," (see 471-000-84). The FUL/SMAC limitation does not apply when the prescribing physician certifies on Form MC-6 that a brand name product is medically necessary and the Department ~~shall~~ will reimburse the pharmacy provider at the EAC value for the trade name drug product. If Form MC-6 is not completed, the Department ~~shall~~ will reimburse the pharmacy at the FUL/SMAC limit for the drug product.

Swallowing disorder assessment, extended: This includes, at a minimum, a comprehensive evaluation by the occupational therapist and extended evaluations by the speech pathologist, nurse, and nutritionist. The need for a psychology evaluation is determined by intake information; the psychology evaluation is billed separately.

Swallowing disorder assessment, brief: The brief assessment includes approximately two hours of time for the occupational therapist, speech pathologist, and nutritionist.

Follow-up visit, brief: This includes a visit with two or more team members.

Follow-up visit, extended: This includes a visit which involves four or more team members.

The team's services are billed under the physician's provider number on Form HCFA-CMS-1500 or the standard electronic Health Care Claim: Professional Transaction (ASC C12N 837). Payment is made according to the Nebraska Medicaid Practitioner Fee Schedule.

The physician services are billed under appropriate CPT codes.

18-004.51 Tobacco Cessation: Medicaid covers tobacco cessation services as practitioner and pharmacy services under the following conditions:

1. Up to two tobacco cessation sessions may be covered in a 12-month period. A session is defined as medical encounters and drug products as listed in items 3 and 4 below. Client access to the Nebraska Tobacco Free Quitline will be unlimited.
2. Nebraska Tobacco Free Quitline: Clients must be enrolled in and active with the Nebraska Tobacco Free Quitline. Referral to the Quitline may be made by a medical professional (physician/mid-level practitioner) or a self referral.
3. Practitioner Office Visits:
 - a. Clients must see their medical care provider (physician/mid-level practitioner) for evaluation particularly for any contraindications for drug products and to obtain prescription(s) if tobacco cessation products are needed.
 - b. (1) In addition to the evaluation under item 3a, a total of four tobacco cessation counseling visits with a medical care provider or tobacco cessation counselor (see 471 NAC 16-002.04) are covered. This may be a combination of intermediate or intensive tobacco cessation counseling visits.
(2) Tobacco cessation counseling provided by a Tobacco Cessation counselor must be ordered by the physician/mid-level practitioner.

4. Tobacco cessation products are covered by Medicaid as a pharmacy service (see 471 NAC 16-000) for those clients 18 years of age or older who require that particular assistance.
 - a. Coverage of drug products used for tobacco cessation is limited to a maximum 90 days supply in one tobacco cessation session. The coverage period is limited to 90 consecutive calendar days, beginning with the date the first prescription for the products is dispensed.
 - b. Tobacco cessation products will only be covered when clients are currently enrolled with and actively participating in the Nebraska Tobacco Free Quitline. Disenrollment or lack of active participation in the Nebraska Tobacco Free Quitline will result in discontinuation of Medicaid coverage of drug products.

18-005 (Reserved)