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CHAPTER 410
OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

FILING CAPTION: Clinical Trial Routine Services Coverage

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RULES:
410-120-1160, 410-120-1200

AMEND: 410-120-1160

NOTICE FILED DATE: 10/11/2022

RULE SUMMARY: The Consolidated Appropriations Act for 2021 amended the Medicaid statute to add a new mandatory benefit for the routine patient costs for items and services furnished in connection with a qualifying clinical trial. These proposed rule changes align state OAR with Federal law.

CHANGES TO RULE:

410-120-1160
Medical Assistance Benefits and Provider Rules ¶

(1) Providers enrolled with and seeking reimbursement for services through the ~~Division of Medical Assistance Programs~~Health Systems Division (Division) are responsible for compliance with current federal and state laws and regulations governing Medicaid services and reimbursement, including familiarity with periodic law and rule changes. The Division's administrative rules are posted on the Oregon Health Authority (Authority) website for the Division and its medical assistance programs. It is the provider's responsibility to become familiar with and abide by these rules.¶
(2) The following services are covered to the extent included in the Division client's benefit package of health care services, when medically or dentally appropriate and within the limitations established by the Division and set forth in the Oregon Administrative Rules (OARs) for each category of ~~Medical~~Health Services:¶
(a) Acupuncture services as described in the Medical-Surgical Services program provider rules (OAR chapter 410, division 130);¶
(b) Administrative examinations as described in the Administrative Examinations and Billing Services program provider rules (OAR chapter 410, division 150);¶
(c) Substance Use Disorder treatment services:¶
(A) The Division covers substance use disorder (SUD) inpatient treatment services for medically managed intensive inpatient detoxification when provided in an acute care hospital and when hospitalization is considered medically appropriate. The Division covers medically monitored detoxification and clinically managed detoxification provided in a free standing detoxification center or an appropriately licensed SUDs residential

treatment facility when considered medically appropriate;¶
(B) The Division covers non-hospital SUD treatment and recovery services on a residential or outpatient basis. For information to access these services, contact the client's PHP or CCO if enrolled, the community mental health program (CMHP), an outpatient substance use disorder treatment provider, the residential treatment program, or the Addictions and Mental Health Division (AMH);¶
(C) The Division does not cover residential level of care provided in an inpatient hospital setting for substance use disorder treatment and recovery;¶
(d) Ambulatory surgical center services as described in the Medical-Surgical Services program provider rules (OAR 410, division 130);¶
(e) Anesthesia services as described in the Medical-Surgical Services program provider rules (OAR chapter 410, division 130);¶
(f) Audiology services as described in the Speech-Language Pathology, Audiology and Hearing Aid Services program provider rules (OAR chapter 410, division 129);¶
(g) Chiropractic services as described in the Medical-Surgical Services program provider rules (OAR chapter 410, division 130);¶
(h) Clinical trials as described in these General Rules:¶
(A) Coverage includes routine patient costs for a beneficiary participating in a qualifying clinical trial or any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the items or services to the beneficiary are covered in the recipient's benefit package;¶
(B) "Qualifying clinical trial" is defined as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition as described in section 1905(gg)(2)(A) of the Act;¶
(C) A qualifying clinical trial is a study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following: ¶
(i) The National Institutes of Health (NIH); ¶
(ii) The Centers for Disease Control and Prevention (CDC); ¶
(iii) The Agency for Health Care Research and Quality (AHRQ); ¶
(iv) The Centers for Medicare & Medicaid Services (CMS); ¶
(v) A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs; ¶
(vi) A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants; ¶
(vii) A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review that the Secretary determines comparable to the system of peer review of studies and investigations used by the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review: ¶
(I) The Department of Energy; ¶
(II) The Department of Veterans Affairs; ¶
(III) The Department of Defense; ¶
(viii) A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; or ¶
(ix) A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet. ¶
(D) Items and Services not included in clinical trial:¶
(i) Routine patient costs do not include any investigational item or service that is the subject of the qualifying clinical trial but is not included in the recipient's OHP benefit package;¶
(ii) Routine patient cost does not include any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise in the recipients OHP benefit package.(i) Dental services as described in the Dental Services program provider rules (OAR chapter 410, division 123);¶
(i) Early and periodic screening, diagnosis, and treatment services (EPSDT) are covered for individuals under 21 years of age as set forth in the individual program provider rules. The Division may authorize services in excess of limitations established in the OARs when it is medically appropriate to treat a condition that is identified as the result of an EPSDT screening;¶
(j) Family planning services as described in the Medical-Surgical Services program provider rules (OAR chapter 410, division 130);¶
(k) Federally qualified health centers and rural health clinics as described in the Federally Qualified Health

Centers and Rural Health Clinics program provider rules (OAR chapter 410, division 147);¶
(~~l~~L) Home and community-based waiver services as described in the Authority and the Department's OARs of Child Welfare (CW), Self-Sufficiency Program (SSP), Addictions and Mental Health Division (AMH), and Aging and People with Disabilities Division (APD);¶
(m) Home enteral/parenteral nutrition and IV services as described in the Home Enteral/Parenteral Nutrition and IV Services program rules (OAR chapter 410, division 148) and related Durable Medical Equipment. Prosthetics, Orthotics and Supplies program rules (OAR chapter 410, division 122) and Pharmaceutical Services program rules (OAR chapter 410, division 121);¶
(n) Home health services as described in the Home Health Services program rules (OAR chapter 410, division 127);¶
(o) Hospice services as described in the Hospice Services program rules (OAR chapter 410, division 142);¶
(p) Indian health services or tribal facility as described in The Indian Health Care Improvement Act and its amendments (Public Law 102-573), and the Division's American Indian/Alaska Native program rules (OAR chapter 410, division 146);¶
(q) Inpatient hospital services as described in the Hospital Services program rules (OAR chapter 410, division 125);¶
(r) Laboratory services as described in the Hospital Services program rules (OAR chapter 410, division 125) and the Medical-Surgical Services program rules (OAR chapter 410, division 130);¶
(s) Licensed direct-entry midwife services as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);¶
(t) Maternity case management as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);¶
(u) Medical equipment and supplies as described in the Hospital Services program, Medical-Surgical Services program, DMEPOS program, Home Health Services program, Home Enteral/Parenteral Nutrition and IV Services program, and other rules;¶
(v) When a client's benefit package includes mental health, the mental health services provided will be based on the Health Evidence Review Commission (HERC) Prioritized List of Health Services;¶
(w) Naturopathic services as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);¶
(x) Nutritional counseling as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);¶
(y) Occupational therapy as described in the Physical and Occupational Therapy Services program rules (OAR chapter 410, division 131);¶
(z) Organ transplant services as described in the Transplant Services program rules (OAR chapter 410, division 124);¶
(aa) Outpatient hospital services including clinic services, emergency department services, physical and occupational therapy services, and any other outpatient hospital services provided by and in a hospital as described in the Hospital Services program rules (OAR chapter 410, division 125);¶
(bb) Physician, podiatrist, nurse practitioner and licensed physician assistant services as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);¶
(cc) Physical therapy as described in the Physical and Occupational Therapy and the Hospital Services program rules (OAR chapter 410, division 131 and 125);¶
(dd) Post-hospital extended care benefit as described in OAR chapter 410, division 120 and 141 and Aging and People with Disabilities (APD) program rules;¶
(ee) Prescription drugs including home enteral and parenteral nutritional services and home intravenous services as described in the Pharmaceutical Services program (OAR chapter 410, division 121), the Home Enteral/Parenteral Nutrition and IV Services program (OAR chapter 410, division 148), and the Hospital Services program rules (OAR chapter 410, division 125);¶
(ff) Preventive services as described in the Medical-Surgical Services program (OAR chapter 410, division 130), the Dental Services program rules (OAR chapter 410, division 123), and prevention guidelines associated with the Health Evidence Review Commission's Prioritized List of Health Services (OAR 410-141-0520);¶
(gg) Private duty nursing as described in the Private Duty Nursing Services program rules (OAR chapter 410, division 132);¶
(hh) Radiology and imaging services as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130), the Hospital Services program rules (OAR chapter 410, division 125), and Dental Services program rules (OAR chapter 410, division 123);¶
(ii) Rural health clinic services as described in the Federally Qualified Health Center and Rural Health Clinic Program rules (OAR chapter 410, division 147);¶
(jj) School-based health services as described in the School-Based Health Services Program rules (OAR chapter

410, division 133);¶
(kk) Speech and language therapy as described in the Speech-Language Pathology, Audiology and Hearing Aid Services program rules (OAR chapter 410, division 129) and Hospital Services program rules (OAR chapter 410, division 125);¶
(LL) Transportation necessary to access a covered medical service or item as described in the Medical Transportation program rules (OAR chapter 410, division 136);¶
(mm) Vision services as described in the Visual Services program rules (OAR chapter 410, division 140).¶
(3) Other Authority or Department, divisions, units, or offices, including Vocational Rehabilitation, AMH, and APD may offer services to Medicaid eligible clients, that are not reimbursed by or available through the Division of Medical Assistance Programs.¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 413.042
Statutes/Other Implemented: ORS 414.025, 414.065

AMEND: 410-120-1200

NOTICE FILED DATE: 10/11/2022

RULE SUMMARY: The Consolidated Appropriations Act for 2021 amended the Medicaid statute to add a new mandatory benefit for the routine patient costs for items and services furnished in connection with a qualifying clinical trial. These proposed rule changes align state OAR with Federal law.

CHANGES TO RULE:

410-120-1200
Excluded Services and Limitations ¶

(1) Certain services or items are not covered under any program or for any group of eligible clients. Service limitations are subject to the Health Evidenced Review Commission (HERC) Prioritized List of Health Services as referenced in OAR 410-141-~~052~~3830 and the individual program chapter 410 OARs. If the client accepts financial responsibility for a non-covered service, payment is a matter between the provider and the client subject to the requirements of OAR 410-120-1280.¶
(2) The Division of Medical Assistance Programs (Division) shall make no payment for any expense incurred for any of the following services or items that are:¶
(a) Not expected to significantly improve the basic health status of the client as determined by Division staff or its contracted entities; for example, the Division's medical director, medical consultants, dental consultants, or Quality Improvement Organizations (QIO);¶
(b) Determined not medically or dentally appropriate by Division staff or authorized representatives, including DMAP's contracted utilization review organization, or are not covered by the Health Evidence Review Commission Prioritized List of Health Services;¶
(c) Not properly prescribed as required by law or administrative rule by a licensed practitioner practicing within his or her scope of practice or licensure;¶
(d) For routine checkups or examinations for individuals age 21 or older in connection with participation, enrollment, or attendance in a program or activity not related to the improvement of health and rehabilitation of the client. Examples include exams for employment or insurance purposes;¶
(e) Provided by friends or relatives of eligible clients or members of his or her household, except when the friend, relative or household member:¶
(A) Is a health professional acting in a professional capacity; or¶
(B) Is directly employed by the client under the Department of Human Services (Department) Aging and People with Disabilities division (APD) Home and Community Based Services or the APD administrative rules, OAR 411-034-0000 through 411-034-0090, governing Personal Care Services covered by the State Plan; or¶
(C) Is directly employed by the client under the Department Child Welfare administrative rules, OAR 413-090-0100 through 413-090-0220, for services to children in the care and custody of the Department who have special needs inconsistent with their ages. A family member of a minor client (under the age of 18) must not be legally responsible for the client in order to be a provider of personal care services;¶
(f) For services or items provided to a client who is in the custody of a law enforcement agency or an inmate of a non-medical public institution, including juveniles in detention facilities, except such services as designated by federal statute or regulation as permissible for coverage under the Division's administrative rules (i.e., inpatient hospitalizations);¶
(g) Needed for purchase, repair, or replacement of materials or equipment caused by adverse actions of adult clients age 21 and over to personally owned goods or equipment or to items or equipment that the Division rented or purchased;¶
(h) Related to a non-covered service; some exceptions are identified in the individual provider rules. If the Division determines the provision of a service related to a non-covered service is cost effective, the related medical service may, at the discretion of the Division and with Division prior authorization (PA), be covered;¶
(i) Considered experimental or investigational, ~~including clinical trials and demonstration projects, or~~ that deviates from acceptable and customary standards of medical practice or for which there is insufficient outcome data to indicate efficacy;¶
(j) Identified in the appropriate program rules including the Division's Hospital Services program administrative rules, Revenue Codes Section, as non- covered services.¶
(k) Requested by or for a client whom the Division has determined to be non-compliant with treatment and who is unlikely to benefit from additional related, identical, or similar services;¶
(l) For copying or preparing records or documents, except those Administrative Medical Reports requested by the branch offices or the Division for casework planning or eligibility determinations;¶

(m) Whose primary intent is to improve appearances, exceptions subject to the HERC coverage and guidelines;¶
(n) Similar or identical to services or items that will achieve the same purpose at a lower cost and where it is anticipated that the outcome for the client will be essentially the same;¶
(o) For the purpose of establishing or reestablishing fertility or pregnancy;¶
(p) Items or services that are for the convenience of the client and are not medically or dentally appropriate;¶
(q) The collection, processing, and storage of autologous blood or blood from selected donors unless a physician certifies that the use of autologous blood or blood from a selected donor is medically appropriate and surgery is scheduled;¶
(r) Educational or training classes that are not intended to improve a medical condition;¶
(s) Outpatient social services except maternity case management services and other social services described as covered in the individual provider rules;¶
(t) Post-mortem exams or burial costs;¶
(u) Radial keratotomies;¶
(v) Recreational therapy;¶
(w) Telephone calls except for:¶
(A) Tobacco cessation counseling as described in OAR 410-130-0190;¶
(B) Maternity case management as described in OAR 410-130-0595;¶
(C) Telemedicine as described in OAR 410-1~~3~~20-~~061~~1990; and¶
(D) Services specifically identified as allowable for telephonic delivery when appropriate in the mental health and substance use disorder procedure code and reimbursement rates published by the Addiction and Mental Health division;¶
(x) Services that have no standard code set as established according to 45 CFR 162.1000 to 162.1011, unless the Division has assigned a procedure code to a service authorized in rule;¶
(y) Whole blood (Whole blood is available at no cost from the Red Cross.); The processing, storage, and costs of administering whole blood are covered;¶
(z) Immunizations prescribed for foreign travel;¶
(aa) Services that are requested or ordered but not provided to the client, unless specified otherwise in individual program rules;¶
(bb) Missed appointments, an appointment that the client fails to keep. Refer to OAR 410-120-1280;¶
(cc) Transportation to meet a client's personal choice of a provider;¶
(dd) Alcoholics Anonymous (AA) and other self-help programs;¶
(ee) Medicare Part D covered prescription drugs or classes of drugs and any cost sharing for those drugs for Medicare-Medicaid Fully Dual Eligible clients, even if the Fully Dual Eligible client is not enrolled in a Medicare Part D plan. See OAR 410-120-1210 for benefit package;¶
(ff) Services provided outside of the United States. Refer to OAR 410-120-1180.
Statutory/Other Authority: ORS 413.042
Statutes/Other Implemented: ORS 414.065, 414.025