State of Vermont
Agency of Human Services
280 State Drive
Waterbury, VT 05671-1000
www.humanservices.vermont.gov

Jenney Samuelson, Secretary
[phone] 802-241-0440
[fax] 802-241-0450

MEMORANDUM

To: Sarah Copeland Hanzas, Secretary of State, Vermont Secretary of State Office
Rep. Trevor Squirrell, Chair, Legislative Committee on Administrative Rules (LCAR)

From: Ashley Berliner, Director of Health Care Policy and Planning, Agency of Human Services (AHS)

Cc: Todd Daloz, Deputy Secretary, Agency of Human Services
Charlene Dindo, Committee Assistant, Legislative Committee on Administrative Rules
Louise Corliss, APA Coordinator, Secretary of State's Office

Date: February 14, 2024

Re: Agency of Human Services Final Proposed Rule Filing

Enclosed is the revised final proposed rule, clean and annotated versions, for Health Care Administrative Rule (HCAR) 4.105, titled Medicaid Coverage of Exception Requests. This rule is also referenced as 23P021.

A memorandum dated January 12, 2024, to the same parties, explains the two changes that were made to the proposed rule in response to public comment and two additional changes that were made to the proposed rule.

In response to an inquiry from Legislative Counsel, AHS has made one additional change to the rule. The change is to remove HCAR 4.105.5(B). This change is highlighted in grey in the revised annotated copy of the revised final proposed rule.

- HCAR 4.105.5(5) was stricken in its entirety. The text that was stricken provides, "A reviewing authority may not reverse the Commissioner's or their designee's decision unless it is determined that the decision was an abuse of discretion."

If you have any questions, please contact Linda Narrow McLemore, Staff Attorney, at Linda.McLemore@Vermont.gov.

INTERPRETIVE MEMO

[X] Medicaid Covered Services Rule Interpretation

[ ] Medicaid Covered Services Procedure Interpretation

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QUESTION: Can a traditional Medicaid beneficiary request coverage of a brand name prescription drug that is presently not available because the manufacturer does not participate in the Federal Drug Rebate Program through the rule 7104 Procedure?

ANSWER: Yes. On July 1, 1999, additional criteria were adopted for the rule 7104 Procedure. The following criteria will be taken into account when reviewing requests for prescription drugs not on a list pre-approved for coverage because the drug manufacturer does not participate in the Federal Drug Rebate Program. If the currently covered drug:

A. has not been effective in treating the patient's medical condition; or

B. causes or is reasonably expected to cause adverse or harmful reactions in the beneficiary.

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QUESTION: Were there any negotiated settlements, decisions reversed by the Human Services Board, Vermont Supreme Court, or favorable rulings from April 1, 1999 through October 1, 2014?

ANSWER: There was one approval for acupuncture and herbal supplements as a result of a negotiated settlement.

There was one rule 7104 denial that was reversed by the Human Services Board ordering the DVHA to pay for a pool pass for one beneficiary.

There was one rule 7104 denial that was reversed by the Human Services Board ordering the DVHA to pay for dentures for one beneficiary.

The Office of Vermont Health Access covered the items specified below, for the requesting individuals only and not for the entire Medicaid population, unless marked with an asterix (*).

*Abdominal Implant – One beneficiary continued to suffer from intractable abdominal pain after exhausting all other pain regimens.

Acupuncture – One beneficiary suffered from long term chronic pain after exhausting all other pain regimens;

One beneficiary, aged two, suffered from a rare liver condition causing skin irritation;

One elderly beneficiary with a history of neurological disorder was unable to take pain medication or engage in traditional therapies;

One beneficiary continued to suffer from severe stump pain despite use of medication (including morphine, neurontin and serotonin enhancing agents), spinal cord stimulation, TENS, nerve block, topical patches, surgical stump revisions, and participation in pain management clinics;

One beneficiary had severe facial pain of unknown etiology requiring extensive pain medication.

*Adaptive Weighted Eating Utensils – One beneficiary experienced neurological decline causing weakness and tremors that interfered with daily activities, including the ability to self-feed.

Air Conditioner – One beneficiary with partial lung removal suffered from Chronic Obstructive Pulmonary Disease with a history of avium pneumonia with increased risk for infection;

~~One beneficiary with significant pulmonary/cardiac disease required cooling/dehumidification to prevent recurrent hospitalization/placement in a nursing home;~~

~~One beneficiary had multiple cardiac, physical, diabetic, renal and pulmonary impairments, morbid obesity, anemia, recurrent ulcerations, COPD, sleep apnea, chronic hypertension, peripheral edema and DJD on oxygen therapy;~~

~~One patient with a history of open heart surgery suffered severe congenital heart disease and recurrent arrhythmias requiring cooling and dehumidification during hot/humid weather preventing hospitalization and placement in a nursing home;~~

~~One beneficiary suffered rare brain damage following excision of a tumor that disrupted thermoregulation of body temperature necessary to maintain organ functioning.~~

~~One beneficiary with multiple complex medical problems including Down syndrome, seizure disorder, history of recurrent aspiration pneumonia, deep vein thrombus, incontinence, MRSA, and was bedridden requiring a high degree of personal care to maintain skin integrity was at risk for serious pulmonary complications and life threatening skin infections.~~

~~One child with cystic fibrosis, alpha-1 antitrypsin deficiency, and malabsorption was at risk for dehydration, electrolyte imbalance, hyponatremia, seizures, and death.~~

~~One child with multiple disabilities including profound mental retardation, mutism, and anhydrosis (inability to sweat) was at risk for heat exhaustion, heat stroke, and death~~

~~One beneficiary with end stage COPD and limited pulmonary function exacerbated by hot humid air and dust was at risk for shortness of breath and emergency hospitalization.~~

~~Air Purifier Two children suffered from congenital cystic fibrosis with asthma and recurrent hospitalizations for breathing problems.~~

~~Banked Breast Milk For a four month period for one infant with microcephaly, rectovaginal fistula, imperforate anus, chromosome anomaly, CHF, horseshoe kidney, poor feeding necessitating the placement of percutaneous gastronomy tube, gastroesophageal reflux, poor growth, allergic colitis, history of febrile urinary tract infection, and formula intolerance. Without banked breast milk the infant was at risk for urinary tract infections, hospitalization, and malnutrition preventing the infant from receiving the surgery necessary to move on to solid foods.~~

~~Brand Name Librium The beneficiary was unable to tolerate the generic form of Librium.~~

~~BiCROS Hearing Aid – One beneficiary with traumatic brain injury, depression and epilepsy who has had a vagus nerve stimulator implanted.~~

~~Brand Name Valium – Three beneficiaries were unable to tolerate the generic form of Valium.~~

~~Cast Crown – One beneficiary with hyperaylasemia was unable to use a resin fabricated crown due to frequent vomiting, and was at risk for sub acute infection, chronic pain and inflammation.~~

~~One beneficiary with severe asthma and severe facial cellulitis with a history of sepsis due to dental infections was at risk for overwhelming sepsis, further abscesses, and infection.~~

~~Chiropractic Treatment – One beneficiary who suffered from Hepatitis C, cirrhosis of the liver, portal hypertension, depression, esophageal varices, addiction and chronic pain from spinal mal alignment failed conservative treatment regimens.~~

~~Completely in the Canal (CIC) Hearing Aids – One beneficiary required nighttime tube feeding, had superior semi circular canal dehiscence with bilateral hearing loss, experienced autophony in one ear, disequilibrium, conductive hearing loss in both ears, severe chronic dry eye syndrome, diplopia, and nystagmus requiring lids need to be physically shut and blocked throughout the night. Beneficiary was at risk of a potentially life threatening event if unable to be awakened by an audible feeding pump alarm alerting to an occluded feeding tube. No other form of hearing aid or feeding pump alarm system was shown to be effective given the beneficiary's complex combination of conditions.~~

~~Contact Lenses – One beneficiary who had an unhealed corneal ulcer following corneal transplant resulting in high myopic astigmatism was at risk for blindness, stereoscopic depth perception and loss of balance. This required one regular and one custom contact lens for correction.~~

~~One beneficiary with keratoconus was at risk for complete vision loss in one eye requiring corneal transplant.~~

~~CPAP Battery – One beneficiary with Ellers Danlos syndrome with severe tracheomalacia required CPAP therapy anytime symptoms arose was at risk for intractable coughing, airway collapse, and hypoxia/syncope.~~

~~Dental Implants – Replacement of an existing dental implant for a beneficiary with an immune deficiency and a history of intestinal problems (including resection of the small bowel, ileostomy, and Hartmann's pouch) who received dentures to masticate food for~~

~~proper nutrition. The approved dentures were affixed to implants that the beneficiary had on both sides, due to the lack of an alveolar ridge.~~

~~One child was underweight, congenitally missing 13 teeth, had years of orthodontic treatment to correct congenital problem, had no success with a variety of removable dental devices, was unable to eat and chew with removable devices, and had a chewing surface that was limited to one side of the mouth. Without dental implants, the child was unable to utilize multiple orthodontic procedures to correct congenital absence of teeth and would have a lifelong problem with chewing, the ability to eat appropriate foods, and the ability to maintain a healthy weight.~~

~~One beneficiary previously approved for dentures had limited gingival bone to hold current dentures in place, difficulty chewing and swallowing food, history of choking episodes, was at high risk of choking, aspiration pneumonia, hypoxia, malnutrition, hospitalization, and death.~~

~~Dental Bridge One beneficiary with a brain injury needed a dental bridge to chew food properly as he has limited ability to cut his food due to reduced functioning from the brain injury.~~

~~Dentures One beneficiary with quadriplegia used teeth for grasping objects in order to perform basic activities of daily living; had chronic stress on the temporomandibular joint because of reduced vertical dimension; was unable to eat adequately, speak adequately, digest food adequately; and was in constant pain from the dysfunctional TMJ. The combination of health conditions placed the beneficiary at a greater risk of aspiration and poor nutrition and compromised the ability to perform basic activities of daily living.~~

~~One beneficiary with a history of GERD (acid reflux disease), dysphasia (difficult and painful swallowing),a hiatus hernia, distal esophageal stricture and mild bulbo-duodenitis had already suffered food impaction due to esophageal dysfunction which put him at a greater risk for aspiration and poor nutrition; the combination of conditions could contribute to a catastrophic event.~~

~~One beneficiary had sleep apnea, diabetes, urinary incontinence, anxiety disorder, PTSD, obesity; had only one functioning kidney; had gastric bypass surgery and a colostomy; and therefore a greater risk of aspiration, poor nutrition and fluctuating blood sugar levels. The combination of health conditions may contribute to a catastrophic event from the underlying diabetes mellitus, which had already been responsible for multiple complications such as gastric paresis, renal disease and coronary artery disease.~~

~~One beneficiary with significant mental retardation consumed foods requiring chewing without realizing they needed to be chewed well. This resulted in severe choking which~~

~~required the Heimlich maneuver. The beneficiary was in danger of further aspiration and possibly hospitalization.~~

~~One beneficiary had a combination of two aortic valve replacements and hepatitis C with interferon which put him at risk for bacterial endocarditis (infection of the heart's valves or inner lining);~~

~~One beneficiary had GERD (gastroesophageal reflux disease), squamous cell carcinoma of the tongue with excision, and COPD (chronic obstructive pulmonary disease). The combination of these conditions was affecting the beneficiary's ability to masticate and swallow food. The beneficiary was at risk of aspiration, given the surgical procedure endured on the tongue and mouth, as well as for infections, given her diminished immune system status;~~

~~One beneficiary had laryngeal cancer and a history of extensive head and neck radiation. The radiation has caused changes in the tissues of the mouth and gums;~~

~~One beneficiary had significant heart and viral liver disease that compromised the immune system risking infection and cardiac deterioration;~~

~~One beneficiary with tracheal aspiration with nectar thickness, forceful cough with incomplete clearing, delayed swallowing, limited laryngeal elevation and poor esophageal stripping wave;~~

~~One beneficiary had cirrhosis of the liver and decreased serum albumin level, pulmonary fibrosis, recurrent infections, compromised immune system and borderline malnutrition with an albumin level of 2.6;~~

~~One beneficiary had a constellation of conditions including mental retardation and esophageal stricture; which has resulted in food impactions requiring endoscopic removal twice in the emergency room;~~

~~One beneficiary had mental retardation, mental illness, and expressive and pervasive developmental disorder who is deaf and does not speak was at risk for episodes of choking and as a result was refusing to eat;~~

~~One beneficiary with a history of Cerebral Palsy and Muscular Dystrophy had a feeding tube secondary to stomach surgery for ulcer disease with resultant small stomach and documented weight loss;~~

~~One beneficiary with diabetes and lung cancer had an aortic valve replacement and required dentures to reduce the risk for systemic infection;~~

~~One beneficiary with an immune deficiency and a history of intestinal problems (including resection of the small bowel, ileostomy, and Hartmann's pouch) needed dentures to masticate food for proper nutrition;~~

~~One beneficiary suffered from hepatic failure for which she is on a transplant list, and had encephalitis, malnutrition and a compromised immune system; Three beneficiaries suffering from mitral valve disorders were at risk for systemic infection, hospitalization, and cardiac deterioration;~~

~~One beneficiary suffered from brachial plexopathy resulting in causalgia, recent pneumonia, depression, fibromyalgia, several infected teeth and weight loss of 50 pounds in six months, which was 30 percent of her body weight;~~

~~One beneficiary with poorly controlled diabetes and advanced dental disease was at risk for choking and a compromised immune system;~~

~~One beneficiary with moderate oral/mild pharyngeal dysphasia suffered repeated choking episodes and had an increased risk of endotracheal aspiration/airway obstruction;~~

~~One beneficiary who had immuno-compromised pulmonary disease was at risk for infection, blocked airway and bacterial endocarditis that jeopardized cardiac status increasing risk for hospitalization or death;~~

~~One beneficiary with squamous cell carcinoma of the tongue required dentures to swallow, reduce choking, chew food and maintain nutrition during treatment course;~~

~~One beneficiary suffered from Stage D, Class IV, Ischemic Dilated Cardiomyopathy requiring dentures to maintain nutrition to prevent congestive heart failure and infection in anticipation of a heart transplant;~~

~~One beneficiary with achalasia, weight loss, dysphasia, esophageal stricture with repeated dilations was at risk for malnutrition and choking without dentures;~~

~~One beneficiary suffering from open mouth wounds was unable to eat causing severe weight loss, increasing risk for infection and further weight loss;~~

~~One beneficiary suffering from Type II diabetes, recurrent Bell's Palsy with severe permanent left sided facial droop/weakness required dentures to help with chewing and swallowing ability;~~

~~One beneficiary with reflux disorder failed conservative treatment requiring esophageal valve surgery and was at risk for decreased food passage and significant weight loss;~~

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~~One beneficiary suffering from traumatic brain injury with limited mobility was at risk for continued choking episodes; One beneficiary who suffered a stroke, and had quadriplegia and esophageal dysmobility, required good dentition for swallowing ability and good nutrition;~~

~~One beneficiary with severe temporomandibular joint disease, reflux disorder, multiple sclerosis with no posterior occlusion, malnutrition, and weight loss was at risk for aspirating on food, continued weight loss, muscle weakness and continued malnutrition;~~

~~One beneficiary with diabetes and renal failure was on dialysis awaiting a transplant, and was immuno-compromised and at risk for bacteremia and possible systemic infection.~~

~~One beneficiary with seizure disorder, ulcerative colitis, chronic abdominal pain, malnutrition, vitamin B12 deficiency, and inability to maintain proper weight after exhausting all conservative measures was at risk for malnutrition, exacerbation of ulcerative colitis, and seizures.~~

~~One beneficiary of significantly advanced age with dementia, osteoporosis, and the inability to eat and speak clearly along with the sudden loss of dentures was at risk for the inability to adjust to an alternative diet, sudden deterioration, malnutrition, and rapid decompensation leading to placement to higher level of care and emergency medical admission for weakness and dehydration.~~

~~One beneficiary with a history of facial trauma, chronic left side temporal pain, maxillary cyst, TMJ bilateral synovitis and dislocation, joint arthrosis, and recidivism of TMJ dysfunction was at risk for continued recidivism of TMJ dysfunction and associated headaches and facial pain, chronic pain, worsening joint arthrosis, digestive dysfunction, and a fostered dependence on narcotic pain medication and physical therapy.~~

~~One beneficiary post renal transplant secondary to ESRD related to diabetic nephropathy and on immunosuppression medications was at risk for oral ulcers, infection, and poor diabetes control which could place their life in jeopardy.~~

~~One beneficiary with diabetes, compromised nutritional status, disabling arthritis, joint deformity, and recovering from brain surgery for cancer followed by treatment with radiation and chemotherapy was at risk for continued weight loss, decreased response to chemotherapy and radiation, and infection of the gums leading to more serious infection due to being immunocompromised.~~

~~One beneficiary had cerebrovascular accident (CVA), dysphagia secondary to CVA, and a history of aspiration pneumonia due to inhalation of food or vomitus. Without dentures, the beneficiary was at risk for repeat aspiration pneumonia leading to hospital admission and treatment with IV antibiotics.~~

~~One beneficiary with hiatal hernia, oropharyngeal dysphagia, GERD, esophageal stricture, and a history of choking and regurgitation of large boluses. Without dentures, the beneficiary was at risk for severe episodes of choking resulting in occlusion of the airway requiring an emergency Heimlich maneuver, café coronary with upper esophageal/oropharyngeal food bolus causing choking and collapse, Barrett's esophagus, and tumor.~~

~~One beneficiary with poorly controlled Type 1 diabetes, high glycated hemoglobin, low BMI, and frequent ulcers of the gums resulting in infection was at risk for osteomyelitis of the jaw, systemic infection sepsis, and atherosclerosis without proper dentition and the ability to adequately control blood sugar with diet.~~

~~One beneficiary with mouth sores, difficulties with speech, and very low BMI was at risk for serious bodily organ dysfunction due to malnutrition.~~

~~One beneficiary with dental abscesses, macrocytosis, hypothyroidism, hypertension, COPD, hyperlipidemia, osteoarthritis, coronary atherosclerosis, and needed a total knee replacement, was at risk for persistent oral infections leading to infected prosthesis resulting in prolonged hospitalization.~~

~~One beneficiary with severe rheumatoid arthritis, severe arthritis of the cervical spine, chronic torticollis, compromised ability to chew and swallow, was wheelchair bound, and had limited use of hands to prepare food was at risk for choking.~~

~~One beneficiary with many serious medical conditions including breast cancer, Barrett's esophagus, chronic lymphocytic leukemia, thyroid disease, diabetes, and TMJ was at risk for infection and malnutrition without dentures.~~

~~One beneficiary with many serious medical conditions including diabetes, fibromyalgia, Lyme disease, anxiety, depression, and chronic PTSD triggered by dental pain was at risk for increased dental infections and increased mental anguish.~~

~~One beneficiary with significant tooth deterioration, severe diabetes, and dysphagia due to advanced Parkinson's disease was at risk for choking.~~

~~One beneficiary with Parkinson's disease and a history of dysphagia was at a significantly increased risk for choking, aspiration, and pneumonia.~~

~~One beneficiary who experienced rapid weight loss, reduction in BMI, and increased symptoms of severe anxiety/depression.~~

~~One beneficiary with an oral-nasal fistula from a cleft palate needed a top denture to stop food and debris from entering his nasal passages in order to prevent chronic infections.~~

~~Denture Relines~~ ~~One beneficiary with end stage liver disease, cirrhosis and ascites was awaiting a liver transplant and at risk for spontaneous bacterial peritonitis risking his chance for successful transplantation.~~

~~Disposable Wipes One elderly beneficiary living at home with congestive heart disease, Alzheimer's, incontinence, hemorrhoids, pressure sores on buttocks and rectal prolapse unable to be surgically corrected, was at risk for infection and placement in a nursing home.~~

~~Eyeglasses One beneficiary had limited nearsightedness remaining in only one eye, limiting vision to 20 feet and severely impacting daily functioning;~~

~~One beneficiary with pseudopapilledema, mild retardation, diabetes, and obesity was at risk for diminished functioning;~~

~~One beneficiary with a tumor in the right medial rectus required excision resulting in visual changes, decreased visual acuity, pain, double vision, eyestrain, bilateral weakness and chronic tearing;~~

~~One beneficiary at the far end of the effects of macular degeneration was blind without correction and unable to care for self and family;~~

~~One beneficiary had early posterior subcapsular cataracts that with correction prevented surgery;~~

~~One beneficiary suffered from recurrent corneal abrasions due to trichiasis with significant photosensitivity and without correction was entirely unable to see;~~

~~One beneficiary had bilateral aphakia, diabetic retinopathy, and severe vitreous hemorrhage status post vitrectomy; One beneficiary with multiple health and ambulatory problems was taking the drug coumadin and was at risk for bleeding after falling if unable to see clearly.~~

~~One beneficiary with significant vision loss without corrected vision was at risk for the loss of independent living and loss of safe mobility.~~

~~Fluoride Trays One beneficiary had oral cancer and was going to start radiation treatment on the right side of the mouth, which eliminates saliva production on that side of the mouth. Xerostomia (dry mouth) from lack of saliva creates an environment that promotes tooth decay and increases the risk of gum disease and chronic open wounds in the mouth if not treated daily with fluoride solution.~~

~~FM System One beneficiary with pseudomonal meningitis and lymphocytic leukemia requiring chemotherapy suffered a medullary stroke causing left-sided paralysis, and was at risk for profound communication deficits leading to developmental delay.~~

~~Gastric Electrical Stimulator – One beneficiary had type I diabetes, diabetic gastroparesis, and related frequent episodes of diabetic ketoacidosis. Beneficiary had been resistant to promotility agents, anti-nausea medication, as well as botulinum toxin injections. Beneficiary had multiple hospital and emergency department visits for dehydration, nausea, and vomiting. Beneficiary was at risk for worsening of digestion (gastroparesis) with continued dehydration, vomiting, nausea, and further episodes of diabetic ketoacidosis which could lead to severe illness or death.~~

~~Genetic Testing Report – One patient suffered from a rare neuromuscular disease making it essential to have this diagnostic tool to diagnose/treat the condition accurately.~~

~~Gingivectomy – A beneficiary with two failed organ transplants needed to be infection-free for a third transplant.~~

~~Home Cholesterol Test Kit – For a six month trial period in compliance with other treatment for one beneficiary with hypercholesterolemia and failure of multiple drug trials was at risk for coronary artery disease, stroke, and heart attack.~~

~~Magnetoencephalography (MEG) Imaging – To pursue a surgical option for treatment of epilepsy for one beneficiary with significantly complicated epilepsy, disability from multiple seizures suffered on weekly basis, and a history of falls and trauma was at risk for progressive/repetitive cerebral anoxia, falls, trauma, and death.~~

~~*Lamb's Wool – One beneficiary suffered from repeated ulcerations between his toes and this was added to coverage, with prescription, for all others similarly situated who need it for padding and to wick moisture away from the skin.~~

~~Methadone Maintenance Treatment – Two beneficiaries found to be compliant with treatment received coverage at an out-of-state facility until the methadone program was established in Vermont.~~

~~Nutriceuticals – A beneficiary with heart and ambulatory problems needed nutriceuticals to assist in producing nitric oxide.~~

~~Oral Reconstruction – One beneficiary with substantial bone loss in the upper jaw required oral reconstruction to chew food.~~

~~Orthodontic Treatment – One beneficiary suffered from a health condition making it difficult to swallow without choking;~~

~~One beneficiary without occlusion had temporomandibular joint disease and orofacial pain requiring a lifelong intraoral appliance to prevent the jaw from locking, and was at risk for irreversible degenerative changes and surgical intervention.~~

~~Partial Dentures and a Palatial Lift – One beneficiary suffered from tongue atrophy and was at risk for aspirating on food;~~

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~~One beneficiary with a hole in the roof of his mouth after repair of a congenital cleft palate was unable to chew food properly, thus increasing the risk of aspirating on food;~~

~~One beneficiary had a history of kidney transplant and diabetes with recurring gum infections with considerable risk for systemic infection due to immune compromised health condition;~~

~~One beneficiary suffered from severe dystonia affecting the ability to control mouth, speech, food intake and good dentition;~~

~~One beneficiary with pancreatitis and who sustained severe injury to the mandible was without occlusion, causing an inability to eat, weight loss and poor nutrition;~~

~~One beneficiary underwent a gastric bypass resulting in a smaller stomach and suffered from diabetes and morbid obesity, requiring partial dentures to chew food to prevent vomiting and compromising the surgical intervention.~~

~~One beneficiary with severe periodontal disease, diabetes, history of stroke, GERD, Barrett's esophagus, hiatal hernia, coronary artery disease with five heart stints, right knee replacement, and breast cancer was at risk for obstruction and hematogenous infection requiring long hospitalization.~~

~~One beneficiary with mouth ulcers, all maxillary teeth removed, and almost all lower teeth intact which were cutting into the upper gums. Without upper dentures, the beneficiary was at risk for continued trauma to upper gums causing bleeding, infections, and bone loss making it impossible for them to ever receive dentures.~~

~~One beneficiary with maxillary teeth removed, experienced significant weight loss, reduction in BMI, and increased symptoms of depression. Without upper dentures, the beneficiary was at risk for continued weight loss, unhealthy (underweight) BMI, and increased mental health concerns.~~

~~One beneficiary with thrush, cancer of the nasal floor and hard palate, and major surgical resection which significantly impacted speech and swallowing. Without an upper denture prosthesis the beneficiary was at risk for infection, significant weight loss, and would have an inadequate seal of the connection between the nose and mouth causing abnormal speech and swallowing.~~

~~One beneficiary with rampant dental caries, periodontal disease, chronic odontogenic pain, and uncontrolled Type II diabetes was at risk for chronic inflammatory periodontal disease, heart disease, pulmonary infections, gastric ulcers, and continued complications of uncontrolled diabetes.~~

~~One beneficiary with over closure of the mandible, loss of vertical dimension of closure, muscles of mastication in spasm, and severe pain and headaches was at risk for further deterioration of the TMJ and constant severe pain without lower dentures.~~

~~One beneficiary with Barrett's Esophagus, gastroesophageal reflux disease, hiatal hernia, and recurrent aspiration pneumonia; was at risk for aspiration and hospitalization.~~

~~One beneficiary with chronic temporal mandibular joint pain, loss of vertical dimension of closure, progressive osteoarthritic changes, severe pain and headaches, at risk of further deterioration of the TMJ and constant severe pain.~~

~~One beneficiary had diabetes and persistent, significant weight loss due to poor nutrition, compounded by infections in the lower anterior teeth. Partial dentures were needed to help maintain body weight, stabilize blood sugar levels, and treat chronic oral infections. This beneficiary also suffered from emotional and anxiety issues related to the above problems.~~

~~Periodontal Surgery~~ ~~One beneficiary suffered gingival hyperplasia from taking drugs for a seizure disorder which increases pocket depths between teeth and gums, causes bleeding, and without periodontal surgery results in disfigurement, infection and tooth loss.~~

~~Prescription Drug Approval~~ ~~Two beneficiaries needed a prescription drug where the manufacturer did not participate in the federal rebate program.~~

~~Prone Stander~~ ~~One beneficiary had multiple congenital health conditions compromised by respiratory and orthopedic disorders;~~

~~One beneficiary with paraplegia, chronic urinary tract infections and skin colonized with Methycillin Resistant Staphylococcus Aureus (MRSA) bacteria was at risk for life-threatening infection without the ability to improve bladder and renal function through standing.~~

~~*Pull-Up Diapers~~ ~~These are approved for children with disabilities and daytime incontinence, age 6 -21, who are accepted into a comprehensive continence training program.~~

~~REAL-Time Continuous Glucose Monitoring System~~ ~~A beneficiary with a total pancreatectomy, gastroparesis, chronic kidney disease, peripheral neuropathy, lack of digestive enzymes, and loss of the early warning signs to prevent and treat emergent low blood glucose, despite excellent compliance, diligence and knowledge about the disease process, was at risk for permanent brain injury or death.~~

~~One child with type I diabetes with widely fluctuating blood glucose levels (requiring frequent testing during the day and overnight) and hypoglycemic unawareness was at risk for life threatening hypoglycemia and hyperglycemia, developing more severe hypoglycemic reactions with less warning, ketonemia, unconsciousness, and emergency hospitalization.~~

One beneficiary with type 1 diabetes, frequent daily hypoglycemic episodes, and diabetic neuropathy which prevented the perception of hypoglycemia was at risk for hypoglycemia unawareness, severe hypoglycemia resulting in unconsciousness, falls, injuries, loss of brain function, coma, and possibly death.

SPES A beneficiary with a recurring tumor refused all forms of treatment other than this naturopathic herbal preparation for prostate cancer.

*Special Needs Infant Feeder Bottles One infant beneficiary with feeding and swallowing disorders was at risk of malnutrition, failure to thrive, aspiration, respiratory infections, and possibly death without nutrition delivered by the proper feeding system.

*Specialized car seats Three children with severe head, neck, and truncal instabilities made it unsafe to use traditional car seats.

Sucraid One beneficiary with sucrose isomaltase and without medication could not absorb sugars which causes pain, was at risk for malnutrition.

Toothette Oral Swabs One child with neuromuscular disease, recurrent fungal mouth ulcers, inability to take liquids orally, inability to swish and rinse mouth, and failed trials of several topical antifungals and oral antifungals was at risk for choking, recurrent fungal mouth ulcers, the need for systemic antifungals, bleeding, mucosal damage, and infection which could spread to deeper structures.

*UVB Light Box This was approved for a beneficiary with a history of severe skin disorder as a less costly alternative to frequent treatments.

UVB Light Box This was approved for a beneficiary with a history of depression, anxiety and suicidality symptoms that were stabilized with the phototherapy. Use of this devise resulted in a marked decrease in accessing emergency services and a decrease in dependency on benzodiazepines, including an eventual remission of symptoms

Medicaid Coverage Exception Requests

#4.105 ~~7104 Requesting Coverage Exceptions~~Medicaid Coverage of Exception Requests
~~(04/01/1999, 98-11F)~~

#4.105.1 General ~~Provisions~~

(A) B~~Any e~~neficiaries who are 21 years old and older may request coverage of a service ~~Medicaid beneficiary may request that the department cover a service or item~~ that Vermont Medicaid ~~is not already included on a list of~~has not already determined to be a covered service. The request should be made ~~to~~using the Medicaid Coverage Exception Request process described by this rule.

1. For beneficiaries who are under 21 years old who request coverage of a service that has not already been determined to be covered, Vermont Medicaid will process the request pursuant to the requirements of HCAR 4.106, Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services.

(B) Filing an Exception Request; Decision on Exception Request

1. ~~covered services and items. The~~ A beneficiary may file an exception request by sending the request~~request~~ and supporting medical documentation ~~should be sent to the Director of the~~to Vermont Medicaid. ~~Office of Vermont Health Access (OVHA). The director~~
2. Vermont Medicaid ~~will review the request and supporting documentation and~~ will make a good faith effort to timely obtain any additional information necessary to determine whether to approve or deny the exception request.
~~1.~~3. ~~quickly to allow the~~The ~~C~~ommissioner of the Department of Vermont Health Access (DVHA) or their designee will make a good faith effort to ~~make a decision~~decide, within thirty days of receipt of the request, to approve or deny the request. ~~within thirty days. In no case will a request for a service or item be approved for coverage unless it is medically necessary.~~

#.4.105.2 Criteria

(A) The request must be for a beneficiary who is 21 years old or older, and the service must:

1. Fit within a category or subcategory of services described at 42 U.S.C. 1396d(a),
2. Be medically necessary pursuant to HCAR 4.101.1(c),
3. Be necessary due to extenuating circumstances that are unique to the beneficiary such that there would be serious detrimental health consequences if the service was not provided, and
4. Have not been reviewed and denied approval by the Federal Drug Administration (FDA), i~~I~~f the service is subject to ~~Federal Drug Administration (FDA)~~FDA approval.~~, the FDA has not reviewed the service and denied its approval.~~

(B) If the requirements of 4.105.2(A) are met, the Commissioner of DVHA or their designee will consider the following additional criteria, in combination, ~~with the above criteria~~in determining whether to approve or deny coverage of the service:~~:~~
~~If, under this section, an individual requests that a service or item be covered, the following criteria will be considered, in combination, in determining whether to cover the service or item for the individual and/or to add it to a list of pre-approved services or items, with the following exception. If the service or item is subject to FDA approval and has not been approved (criterion (I)9 below), the request for coverage of the service or item will be denied.~~

1. The service has not been identified in administrative rule or statute as a non-covered service, or, if the

service has been identified as non- covered and a reason for its non-coverage includes its lack of efficacy, then there has been credible and material new evidence about the efficacy of the service since it was identified as non-covered.

2. The service fits within a category or subcategory of services described at 42 U.S.C. 1396d(a) that is offered by Vermont Medicaid for adults,
3. The service is consistent with the objective of the Medicaid Act (Title XIX of the Social Security Act), to provide medical assistance to eligible individuals.
4. Denial of the service would be arbitrary. Vermont Medicaid may not deny coverage for a service solely based on its cost. ~~Vermont Medicaid may not deny coverage for a service solely based on diagnosis, illness, or condition, or solely based on its cost.~~
5. The service is not experimental or investigational.
6. The medical appropriateness and efficacy of the service has been demonstrated in credible scientific evidence published in peer-reviewed literature or by medical experts in the relevant clinical field.
7. Less expensive, medically appropriate alternatives are not available, or have been trialed and failed, or are contraindicated for the beneficiary.
8. The service is primarily and customarily used to serve a medical purpose, and it is generally not useful to an individual in the absence of an illness, injury, or disability.~~Are there extenuating circumstances that are unique to the beneficiary such that there would be serious detrimental health consequences if the service or item were is not provided?~~

~~Does the service or item fit within a category or subcategory of services offered by the Vermont Medicaid program for adults?~~

~~Has the service or item been identified in rule as not covered, and has new evidence about efficacy been presented or discovered?~~

~~Is the service or item consistent with the objectives of Title XIX?~~

9. If the request is for a brand-name prescription drug that is not covered~~theof drugs~~ because the drug manufacturer does not participate in the Federal Drug Rebate Program, then coverage of this drug must be needed because the currently covered drug has not been effective in treating the beneficiary's medical condition or causes or is reasonably expected to cause adverse or harmful reactions in the beneficiary.

~~has? Is there a rational basis for excluding coverage of the service or item? The purpose of this criterion is to ensure that the department does not arbitrarily deny coverage for a service or item. The department may not deny an individual coverage for a service or item solely based on its cost.~~

~~Is the service or item experimental or investigational?~~

~~for MedicaidHave the medical appropriateness and efficacy of the service or item been demonstrated in the literature or by experts in the field?~~

~~1. Are less expensive, medically appropriate alternatives not covered or not generally available?~~

~~Is FDA approval required, and if so, has the service or item been approved?~~

~~2. Is the service or item primarily and customarily used to serve a medical purpose, and is it generally not useful to an individual in the absence of an illness, injury, or disability?~~

#4.105.3 Outcomes

~~(A) Each decision shall result in one of four~~ 4 outcomes. ~~The four~~ 4 ~~possible outcomes are:~~

(A) ~~(1) T~~the ~~C~~commissioner or their designee will approve or ~~deny~~s coverage of the service ~~service or item~~ for the ~~individual~~ beneficiary.

(B) For approvals and denials in the exception request process, the Commissioner or their designee~~and adds it to a list of pre-approved services or items~~will determine whether to pursue administrative processes (e.g., state plan am~~ended~~endment, administrative rule) that are necessary to cover the service by Vermont Medicaid.~~;~~

~~1. (2) Tthe Ccommissioner approves coverage of the service or item for the individual and does not add it to a list of pre-approved services or items,;~~

~~2. (3) Tthe Ccommissioner does not approve coverage of the service or item for the individual and adds it to a list of pre-approved services or items,; or~~

~~3. (4) Tthe Ccommissioner does not approve coverage of the service or item for the individual and does not add it to a list of pre-approved services or items.~~

~~If the Ccommissioner's decision is to add the service or item to a pre-approved list of covered services, an Interpretive Memo will be issued delineating the addition. All such Interpretive Memos will be incorporated into the rule as soon as practical.~~

#.4.105.4 Approvals

(A) Annually, ~~The Office of Vermont Health Access~~ ~~DVHA~~Vermont Medicaid ~~shall~~will ~~, semiannually, issue~~publish on the DVHA website a ~~report~~ document updating the list~~ing~~ of ~~all affirmative~~the approved coverage decisions ~~made~~ under the ~~ethis~~ exception request ~~procedure~~ process that do not result in the service ~~or item that is authorized being added to a list of pre-approved~~being considered for pursuit of coverage by Vermont Medicaid, as described at ~~services or items~~4.105.3(B).

~~(A)~~(B) ~~This list shall include the Ccommissioner's coverage decisions, plus negotiated settlements and Human Services Board and Vermont Supreme Court decisions. Because this list shall be available for public inspection, it shall be composed in a manner that protects beneficiaries' right to confidentiality. The~~ ~~Demortment~~DVHAVermont Medicaid will ensure that all Medicaid beneficiaries who are similarly situated to the individual who has obtained coverage pursuant to the exceptions request process are ~~will be~~ treated similarly with respect to coverage of the same service ~~or item~~.

#.4.105.5 Adverse Decisions

(A) ~~An adverse decision from~~Vermont Medicaid will inform a beneficiary who receives an adverse decision of their right to appeal ~~Ccommissioner may be appealed~~ through the State fair hearing process.

~~(B) A reviewing authority may not reverse the Commissioner's or their designee's decision unless it determines that the decision was an abuse of discretion.~~

~~(C)~~(B) A request for a service for which there has been an ~~n~~ adverse decision may not be ~~renewed by~~renewed by the same beneficiary until twelve months have elapsed since the previous final decision or until one of the following has been demonstrated:

1. N~~n~~ew documentation of the individual's condition that was not available at the time of the prior request~~,~~,
2. ~~a~~A material change in the individual's condition,~~,~~
N~~n~~ew and material medical evidence, o~~r~~r
3.
4. ~~a~~A material change in technology has been demonstrated.

~~The Office of Vermont Health Access shall, semiannually, issue an Interpretive Memo updating the listing of all affirmative coverage decisions made under this procedure that do not result in the service or item that is authorized being added to a list of pre-approved services or items. This list shall include the commissioner's coverage decisions, plus negotiated settlements and Human Services Board and Vermont Supreme Court decisions. Because this list shall be available for public inspection, it shall be composed in a manner that protects beneficiaries right to confidentiality. The department will ensure that all Medicaid beneficiaries who are similarly situated to the individual who has obtained coverage will be treated similarly with respect to coverage of the same service or item.~~

~~If, under this section, an individual requests that a service or item be covered, the following criteria will be considered, in combination, in determining whether to cover the service or item for the individual and/or to add it to a list of pre-approved services or items, with the following exception. If the service or item is subject to FDA approval and has not been approved (criterion (I) below), the request for coverage of the service or item will be denied.~~

~~(A) Are there extenuating circumstances that are unique to the beneficiary such that there would be serious detrimental health consequences if the service or item were not provided?~~

~~(B) Does the service or item fit within a category or subcategory of services offered by the Vermont Medicaid program for adults?~~

~~(C) Has the service or item been identified in rule as not covered, and has new evidence about efficacy been presented or discovered?~~

~~(D) Is the service or item consistent with the objectives of Title XIX?~~

~~(E)~~(A) ~~Is there a rational basis for excluding coverage of the service or item? The purpose of this criterion is to ensure that the department does not arbitrarily deny coverage for a service or item. The department may not deny an individual coverage for a service or item solely based on its c~~ost.~~~~

Medicaid Coverage Exception Requests

4.105 Medicaid Coverage of Exception Requests

4.105.1 General

(A) Beneficiaries who are 21 years old and older may request coverage of a service that Vermont Medicaid has not already determined to be a covered service. The request should be made using the Medicaid Coverage Exception Request process described by this rule.

1. For beneficiaries who are under 21 years old who request coverage of a service that has not already been determined to be covered, Vermont Medicaid will process the request pursuant to the requirements of HCAR 4.106, Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services.

(B) Filing an Exception Request; Decision on Exception Request

1. A beneficiary may file an exception request by sending the request and supporting medical documentation to Vermont Medicaid.
2. Vermont Medicaid will make a good faith effort to timely obtain any additional information necessary to determine whether to approve or deny the exception request.
3. The Commissioner of the Department of Vermont Health Access (DVHA) or their designee will make a good faith effort to decide, within thirty days of receipt of the request, to approve or deny the request.

4.105.2 Criteria

(A) The request must be for a beneficiary who is 21 years old or older, and the service must:

1. Fit within a category or subcategory of services described at 42 U.S.C. 1396d(a),
2. Be medically necessary pursuant to HCAR 4.101.1(c),
3. Be necessary due to extenuating circumstances that are unique to the beneficiary such that there would be serious detrimental health consequences if the service was not provided, and
4. Have not been reviewed and denied approval by the Federal Drug Administration (FDA), if the service is subject to FDA approval.

(B) If the requirements of 4.105.2(A) are met, the Commissioner of DVHA or their designee will consider the following additional criteria, in combination, in determining whether to approve or deny coverage of the service:

1. The service has not been identified in administrative rule or statute as a non-covered service, or, if the service has been identified as non- covered and a reason for its non-coverage includes its lack of efficacy, then there has been credible and material new evidence about the efficacy of the service since it was identified as non-covered.
2. The service fits within a category or subcategory of services described at 42 U.S.C. 1396d(a) that is offered by Vermont Medicaid for adults,
3. The service is consistent with the objective of the Medicaid Act (Title XIX of the Social Security Act), to provide medical assistance to eligible individuals.
4. Denial of the service would be arbitrary. Vermont Medicaid may not deny coverage for a service solely based on its cost.
5. The service is not experimental or investigational.
6. The medical appropriateness and efficacy of the service has been demonstrated in credible scientific evidence published in peer-reviewed literature or by medical experts in the relevant clinical field.
7. Less expensive, medically appropriate alternatives are not available, or have been trialed and failed,

or are contraindicated for the beneficiary.

8. The service is primarily and customarily used to serve a medical purpose, and it is generally not useful to an individual in the absence of an illness, injury, or disability.
9. If the request is for a brand-name prescription drug that is not covered because the drug manufacturer does not participate in the Federal Drug Rebate Program, then coverage of this drug must be needed because the currently covered drug has not been effective in treating the beneficiary's medical condition or causes or is reasonably expected to cause adverse or harmful reactions in the beneficiary.

4.105.3 Outcomes

(A) The Commissioner or their designee will approve or deny coverage of the service for the beneficiary.

(B) For approvals and denials in the exception request process, the Commissioner or their designee will determine whether to pursue administrative processes (e.g., state plan amendment, administrative rule) that are necessary to cover the service by Vermont Medicaid.

4.105.4 Approvals

(A) Annually, Vermont Medicaid will publish on the DVHA website a document updating the list of the approved coverage decisions made under the exception request process that do not result in the service being considered for pursuit of coverage by Vermont Medicaid, as described at 4.105.3(B).

(B) Vermont Medicaid will ensure that all Medicaid beneficiaries who are similarly situated to the individual who has obtained coverage pursuant to the exceptions request process are treated similarly with respect to coverage of the same service.

4.105.5 Adverse Decisions

(A) Vermont Medicaid will inform a beneficiary who receives an adverse decision of their right to appeal through the State fair hearing process.

(B) A request for a service for which there has been an adverse decision may not be renewed by the same beneficiary until twelve months have elapsed since the previous final decision or until one of the following has been demonstrated:

1. New documentation of the individual's condition that was not available at the time of the prior request,
2. A material change in the individual's condition,
3. New and material medical evidence, or
4. A material change in technology has been demonstrated.