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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

~~Medicaid Covered Services Rule
Interpretation~~

~~Medicaid Covered Services Procedure
Interpretation~~

~~This interpretive memo remains effective statewide until it is specifically superseded either by a subsequent interpretive memo or by a contradictory rule with a later date.~~

~~Reference 7104 Date of this Memo 07/01/1999 Page 1 of 1~~

~~This Memo: is New Replaces one dated _____~~

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.~~

INTERPRETIVE MEMO

~~[X] Medicaid Covered Services Rule Interpretation~~

~~[] Medicaid Covered Services Procedure Interpretation~~

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Reference ~~7104~~ Date of this Memo ~~10/1/2014~~ Page ~~1 of 13~~

This Memo: ~~[] is New~~ ~~[X] Replaces one dated~~ ~~4/1/2014~~

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;~~

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This Memo: is New Replaces one dated 4/1/2014

~~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.~~

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~~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 Ehlers-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~~