UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

W.B., by and through his father and legal guardian David B., and A.W., by and through her mother and legal guardian, Brittany C., on behalf of themselves and all others similarly situated,

Plaintiffs, Case No.:

v.

SIMONE MARSTILLER, in her official capacity as Secretary for the FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,

Defendant.
_____/

W.B.'S MOTION FOR A PRELIMINARY INJUNCTION

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, class member and minor child W.B., by and through his father, David B., moves for entry of a preliminary injunction and in support thereof files this Memorandum of Law with supporting exhibits.

MEMORANDUM OF LAW IN SUPPORT OF MOTION

W.B. seeks to redress the harm Defendant imposed on him when Defendant denied W.B.'s request for Medicaid services relying solely on Defendant's standard of medical necessity set forth in Fla. Admin. Code R. 59G-1.010. Four

separate Florida state court decisions have found Defendant's standard to be more restrictive than what is allowed for under federal Medicaid law. More specifically, the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) provisions of the federal Medicaid Act, 42 U.S.C. §§ 1396a(a)(43) & 1396d(r), mandate states to provide all medically necessary services necessary to correct or ameliorate the health conditions of child Medicaid beneficiaries. Rather than rely on its illegal medical necessity standard, had Defendant instead, met her obligation under EPSDT, W.B. would have easily established his need for the requested service. Due to the significant risks that Defendant's actions pose to W.B.'s health, however, he cannot wait for final judgment to rectify this harm; thus, he makes this request for preliminary relief.

In support of this motion, W.B. shows the Court as follows:

I. STATEMENT OF FACTS

W.B. is a one-year-old Medicaid recipient enrolled in the Florida Managed Care Organization known as the Children's Medical Services Health Plan (CMS Plan). The CMS Plan is administered by WellCare Health Plans, Inc. through a contract with the Defendant under Florida's Statewide Medicaid Managed Care Program. *See* Fla. Stat. § 409.971.

W.B.'s rare genetic disorder, CHARGE syndrome, presents in less than one out of 10,000 live births in the United States. As a result of his diagnosis, W.B. has

multiple congenital anomalies including coloboma, choanal atresia, facial palsy, chronic lung disease, a soft larynx that partially obstructs his airway, hypoparathyroidism, dysphagia, GERD, and developmental delay. (Ex. 2, 3, 4 & 5).

W.B. uses a gastronomy tube (g-tube) for his nutritional needs. (Ex. 2). He attends a Prescribed Pediatric Extended Care center during the day that providers nursing services, personal care, and developmental therapies. (Ex. 3). While he receives care from an excellent team of specialists in Florida, none have expertise in treating CHARGE Syndrome and all agree that, unless he receives an extensive multidisciplinary evaluation by treating providers who have expertise in CHARGE, he risks further medical and developmental setback. (Ex. 4, 5, & 6).

To further W.B.'s treatment goals, on September 9, 2020, W.B.'s pediatrician, Dr. Stephanie Carlin, prescribed W.B. outpatient hospital services at the CHARGE Center in Cincinnati, Ohio. (Ex. 4). The CHARGE Center, run by Cincinnati's Children's Hospital, is a one-of-a-kind facility that uses a multidisciplinary approach to coordinate care among subspecialists who have specific, up-to-date expertise in treating CHARGE Syndrome, including genetics, ophthalmology, cardiology, plastic surgery, and Ear, Nose, and Throat (ENT). The members of W.B.'s Florida aerodigestive team including W.B.'s ENT, Dr. Andrew Simonsen, and his pulmonologist, Dr. Gerardo Vazquez Garcia, have stated that

they do not have the specialized expertise required to thoroughly address the complications caused by W.B.'s CHARGE syndrome. (Ex. 5 & 6).

In evaluating Dr. Carlin's request for Medicaid to approve W.B.'s evaluation and treatment at the CHARGE Center, the CMS Plan applied Defendant's medical necessity standard stating:

> We made our decision because: We determined that your requested services are not medically necessary because the services do not meet the reason(s) checked below: (See Rule 59G-1.010)
>
> *Must be able to be the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide,
> *Must be furnished in a manner not primarily intended for the convenience of the recipient, caretaker, or provider. (The convenience factor is not applied to the determination of the medically necessary level of private duty nursing (PDN) for children under the age of 21.)"[1]

(Ex. 7)

The CMS Plan further justified its denial on the basis that:

> "we received a request to authorize treatment for your child with an out of network provider, Dr. Catherine Hart at Cincinnati Children's Hospital. We did not approve the request for authorization because out of network services are not a covered benefit when services are available

[1] Under its contract with Defendant to administer Florida's Medicaid program, the CMS Plan used Defendant's medical necessity standard in Fla. Admin. Code R. 59G-1.010 to deny W.B.'s request for Medicaid coverage of services at the CHARGE Center. [AHCA MCO Contract, WellCare Coverage Policy Guidelines].

> within your plan. This service can be provided by one of the following in network providers…."

(*Id.*)

In its denial, the CMS Plan did not name specific "in network providers" but stated that W.B. could access pulmonology and ENT specialists through either the UFHealth System or Nemours Children's Hospital. (*Id.*) Notably, Dr. Carlin works for the UFHealth System and W.B.'s pulmonologist, Dr. Vazquez Garcia, works for Nemours. (Ex. 4 & 5) As stated above, neither have expertise in treating CHARGE and both strongly recommend W.B. receive care at the CHARGE Center. (*Id.*)

On October 15, 2020, Dr. Carlin's office filed an appeal on behalf of W.B. requesting that the CMS Plan overturn its denial and authorize services at the CHARGE Center. (Ex. 8). In the appeal, Dr. Carlin specifically responded to the CMS Plan finding that W.B. can be served by individual in-network providers:

> "there are no CHARGE centers in network that have a multidisciplinary team of providers who specialize in CHARGE. [W.B.] has had a complicated clinical course and his care would benefit from a multidisciplinary team approach to ensure that we are maximizing his care locally."

(*Id.*)

On November 13, 2020, the CMS Plan denied Dr. Carlin's appeal. (Ex. 9). As of the time of this filing, Defendant continues to deny W.B.'s request for Medicaid to cover outpatient hospital services at the CHARGE Center.

III. ARGUMENT

W.B. meets the Eleventh Circuit's standard for entry of preliminary injunctive relief. W.B. demonstrates: (1) a substantial likelihood of success on the merits; (2) irreparable injury; (3) that the threatened injury to him outweighs any injury to the Defendants; and (4) that the issuance of an injunction is not adverse to the public interest. *See, e.g., Odebrecht Const., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1273-74 (11th Cir. 2013). As established below, these factors are present here.

A. There is a substantial likelihood that W.B. will prevail on the merits of his claim that Defendant's denial of outpatient hospital services at the CHARGE Center violates his rights under EPSDT.

1. Defendant is obligated under EPSDT to provide W.B. all Medicaid services necessary to correct or ameliorate his health condition.

The Medicaid Act mandates that states participating in the Medicaid program provide EPSDT services to Medicaid-eligible children under 21 years of age. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B),1396a(a)(43) & 1396d(r). Under EPSDT, children must receive all services covered by the Medicaid Act that are necessary to correct or ameliorate any physical and mental illnesses and

conditions. *Id.*; *see also Pittman*, 998 F.2d 887, 889 (11th Cir. 1993). The State must provide any service covered by EPSDT "whether or not such services are covered under the state plan." *Id*. In other words, the Medicaid Act requires that participating states must "cover every type of health care or service necessary for EPSDT corrective or ameliorative purposes that is allowable under § 1396d(a)." *Moore ex rel. Moore v. Reese,* 637 F.3d 1220, 1233-34 (11th Cir. 2011). The outpatient hospital services requested by W.B. are a service covered by 42 U.S.C. § 1396d(a). 42 U.S.C. §§ 1396d(a)(2)(A). Furthermore, federal Medicaid regulations require that Florida's Medicaid program:

> …pay for services furnished in another State to the same extent that it would pay for services furnished within its boundaries if the services are furnished to a beneficiary who is a resident of the State, and any of the following conditions is met…[t]he State determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other State….

42 C.F.R. § 431.52.

2. W.B.'s treating physician has demonstrated the medical necessity of W.B.'s treatment at the CHARGE Center.

As detailed by Dr. Carlin, W.B.'s CHARGE diagnosis is extremely rare and affects multiple organ systems; referred to by Dr. Vazquez Garcia as creating a constellation of conditions which will require subspecialist and therapeutic interventions for W.B.'s entire life. (Ex. 5). Despite the expertise of W.B.'s

subspecialists in Florida, in W.B.'s short life, he has experienced four hospital admissions, three emergency room visits, and been admitted for observation three times. (*Id*.)

Dr. Carlin specifies that the CHARGE Center is the only of its kind and "is able to coordinate medical consultations between the many specialists [including genetics, ophthalmology, cardiology, ENT, and plastic surgery] involved in the care of a child with CHARGE Syndrome." (Ex. 4). This coordination also ensures that "visits, testing, and evaluations are done in a sensible sequence, minimizing the risk by consolidating anesthesia events and blood draws." (*Id.*)

In response to the CMS Plan denial on the basis that W.B. can receive equally effective care in Florida, Dr. Carlin states that "unfortunately, there are no CHARGE Centers in network that have a multidisciplinary team of providers who specialize in CHARGE" and W.B. "has had a complicated clinical course and his care would benefit from a multidisciplinary approach to ensure that we are maximizing his care locally." (Ex. 8).

Dr. Carlin makes the case that care at the CHARGE Center is necessary to correct and ameliorate the health conditions caused by W.B.'s diagnosis of CHARGE. (Ex. 4 & 8). Specifically, she asserts that it "would be detrimental to W.B.'s health to be excluded…" and that the streamlined treatment at the Center is essential to help W.B. "avoid developmental setbacks." (*Id.*) Dr. Vazquez Garcia

agrees, stating that W.B. "should be evaluated without further delay at the CHARGE Center at Cincinnati Children's where they have expertise not available anywhere in Florida." (Ex. 5). Thus, as established by his treating providers, the CHARGE Center is Medicaid service necessary to correct and ameliorate W.B.'s "constellation of conditions." (Ex. 4, 5 & 6).

3. The standard on which Defendant relied to evaluate W.B.'s request for care at the CHARGE Center violates EPSDT.

As noted under the Medicaid Act, children must receive all services listed in 42 U.S.C. § 1396d(a) necessary "to correct or ameliorate" a health condition. *See* 42 U.S.C. § 1396d(r)(5). Federal courts have interpreted "ameliorate" to mean the same as the term's common dictionary definition, that is "to make better or more tolerable." *Ekloff v. Rodgers*, 443 F. Supp. 1171, 1180 (U.S.D.C. Az. 2006) (internal quotations omitted). The thrust behind requiring states to cover Medicaid services for children under this broad standard is to "assure that health problems found are diagnosed and treated early, before they become more complex and their treatment more costly." *Id.* (citing the CMS State Medicaid Manual, § 5010.B.).

In administering EPSDT, while states are "permitted (but not required) to set parameters that apply to the determination of medical necessity in individual cases…those parameters may not contradict or be more restrictive than the federal [EPSDT] statutory requirement." U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs. (CMS), *EPSDT: A Guide for States: Coverage in the*

Medicaid Benefit for Children and Adolescents at 23 (June 2014) (hereinafter, "EPSDT Guide").[2]

In evaluating the medical necessity of services under EPSDT, "the treating physician is a 'a key figure' and initially determines what…services are medically necessary." *M.H. v. Berry*, No. 1:15-CV-1427-TWT, 2021 WL 1192938 *6 (N.D. Ga. March 29, 2021). While both the state and treating physician have a role to play in determining medical necessity, states are "not empowered to act as the 'final arbiter' of medical necessity to arbitrarily ignore the reasons given in the treating physician's recommendation of…[medical services]." *Id.*; *see also*, *Moore*, 637 F.3d at 1258-59 ("[w]hile Congress could have conferred the 'final arbiter' role to the state, it did not.").

Defendant has adopted a medical necessity standard under Fla. Admin. Code R. 59G-1.010 that it applies to authorizations for Medicaid services regardless of whether the evaluation relates to coverage for an adult or for a child. (Ex. 11; Dkt. #1; *see also*, *C.F. v. Dep't of Children and Families*, 934 So.2d 1, 5 (Fla. 3d DCA 2005). Defendant's definition sets parameters that contradict and are more restrictive than what is allowed for under EPSDT, a conclusion drawn time and time again by Florida courts. *See C.F.* at 7 (in evaluating whether a state agency

[2]The EPSDT Guide can be accessed online at: *http?www.medicaid.gov/medicaid/benefits/downloads/epsdt_coverage_guide.pdf.*

correctly analyzed a child's need for Medicaid services under Fla. Admin. Code R. 59G-1.010, the court held that the agency "incorrectly used more restrictive definitions of 'medical necessity'…than federal law requires"); *see also*, *Q.H. v. Sunshine State Health Plan*, 307 So.3d 1, 14 (Fla. 4th DCA 2020) (finding that the state "erred in applying the 'overly restrictive' definition of medical necessity set forth in the Florida Administrative Code, rather than the more expansive EPSDT standard of whether the treatment was necessary to 'correct or ameliorate the child's condition"); *I.B. v. Agency for Health Care Admin.*, 87 So.3d 6, 8-10 (Fla. 3d DCA 2012); and *E.B. v. Agency for Health Care Admin.*, 94 So.3d 708, 708-709 (Fla. 4th DCA 2012).

Furthermore, Defendant takes the erroneous position that AHCA is the final arbiter of medical necessity for all Medicaid services regardless of whether the service is prescribed for a child under age 21. *See* Fla. Admin. Code R. 59G-1.053 (AHCA "is the final arbiter of medical necessity for the purposes of determining Florida Medicaid reimbursement…"); (*see also*, Ex. 11) (in evaluating its EPSDT obligations under state and federal law, Defendant concludes that "…a treating physician's opinion regarding the medical necessity of a service is not dispositive or accorded deference."). By adopting this position, Defendant fails to accord proper weight or deference to the opinions of treating physicians in prescribing

Medicaid services for children under age 21, a requirement under EPSDT. *M.H.* 2021 WL 1192938 at *6; *Moore*, 637 F.3d at 1258-59.

W.B.'s case was no exception in Defendant's application of her overly restrictive medical necessity standard to Medicaid enrolled children under age 21. Per Defendant's adopted policy, rather than assess whether W.B.'s request for outpatient hospital services was necessary "to correct or ameliorate" his health conditions, Defendant – through its contractor, the CMS Plan – subjected W.B.'s request to the more stringent standard found in Fla. Admin. Code R. 59G-1.010. (Ex. 7).

The CMS Plan, relying on Defendant's definition, dismissed W.B.'s request on the basis that treatment through his local subspecialists, including pulmonology and ENT is sufficient to meet his needs. (*Id*.) The CMS Plan affirmed this conclusion in their response to W.B.'s appeal of the initial denial without giving consideration or weight to Dr. Carlin's response that W.B.'s specialists in Florida do not have expertise in treating CHARGE syndrome and, therefore, continued denial of W.B.'s care at the CHARGE Center would be detrimental to his health. (Ex. 7, 8 & 9). While the CMS Plan did not name specific providers, the health systems it identified – UFHealth and Nemours – are both systems from which W.B. already receives care and whose providers have recommended that he receive care at the CHARGE Center. (Ex. 4 & 5).

Had Defendant, at any stage of evaluating W.B.'s request for Medicaid coverage, applied the correct standard – that is whether the evaluations and treatment at the CHARGE Center is necessary to correct or ameliorate W.B.'s complex clinical course resulting from his CHARGE diagnosis and, if so, whether continuing treatment by his subspecialists in Jacksonville was an equally effective treatment plan – the information provided by Dr. Carlin would have established that the CHARGE Center would serve to make W.B.'s health conditions more tolerable and assure his health problems are addressed early "before they become more complex and their treatment more costly." *Ekloff*, 443 F. Supp. at 1171; *see also*, *C.F.*, 934 So.2d 1at 7; *Q.H.*, 307 So.3d at 14; *I.B.*, 87 So.3d at 6; *E.B.*, 94 So.3d at 708.

Additionally, Defendant cannot graft on a further requirement – outside whether the service is necessary to correct or ameliorate a child's health condition – that W.B. prove that obtaining the service from an out-of-state provider is not simply a matter of convenience for his parents. *See Jackson v. Millstone*, 801 A.2d 1034, 1049 (Md. 2002)*; M.H.,* 2021 WL 1192938 at *7 (finding that the state should determine whether a service is "medically necessary…based on whether a service is medically necessary to correct or ameliorate a beneficiary's condition"

and not "based upon non-medical criteria").[3] Instead, pursuant to EPSDT, the state must cover W.B.'s requested outpatient hospital services at the CHARGE Center because they are necessary to correct and ameliorate his health condition. Therefore, W.B. has a substantial likelihood of success on the merits of his claims under the Medicaid Act.

B. W.B. will suffer immediate and irreparable harm because of Defendant's denial of his prescribed specialty outpatient hospital services.

Courts have consistently found that "[t]he denial of medical benefits and resultant loss of essential medical services, constitutes an irreparable harm..." *Edmunds v. Levine*, 417 F. Supp. 2d 1323, 1342 (S.D. Fla. 2006) (citing *Cramer v. Chiles*, 33 F. Supp.2d 1342, 1349 (S.D. Fla.1999)); *Mitson v. Coler*, 670 F. Supp. 1568, 1577 (S.D. Fla.1987); *Dodson v. Parham*, 427 F. Supp. 97, 108 (N.D. Ga.1977); *see also, e.g., Beltran v. Myers*, 677 F.2d 1317, 1322 (9th Cir.1982); *Newton–Nations v. Rogers*, 316 F. Supp. 2d 883, 888 (D. Ariz. 2004); *Doe v. Perales*, 782 F. Supp. 201, 204–205 (W.D.N.Y.1991); *Benjamin H. v. Ohl*, No. 3:99–0338, 1999 WL 34783552, *12 (S.D.W.V. July 15, 1999); *Mass. Ass'n of Older Americans v. Sharp*, 700 F.2d 749, 753 (1st Cir. 1983). This includes denial of EPSDT benefits. *See K.G. ex rel. Garrido v. Dudek*, 839 F. Supp. 2d 1254, 1278

[3] The CMS Plan also did not provide any analysis in its notice denying W.B. services at the CHARGE Center regarding whether the requested services were actually convenient.

(S.D. Fla. 2011); *O.B. v. Norwood*, 170 F. Supp. 3d 1186, 1196 (U.S.D.C. N.D. Ill. 2016).

The statement of his treating provider shows that W.B. is currently suffering harm because he is not receiving the service that his treating provider recommended. (Ex. 3, 4, 5 & 6). Moreover, he has demonstrated that his health and well-being are in immediate jeopardy without the outpatient hospital services prescribed by his treating physician to manage his many complex care needs, make his condition more tolerable, and keep him safe and healthy. (*Id.*) W.B. is diagnosed with an exceedingly rare genetic disorder that has caused significant health conditions across multiple organ systems. (Ex. 2). In less than the first two years of his life, he has been admitted to the hospital over a half dozen times. (Ex. 3 & 5). His treating physicians are adamant that the coordinated evaluation and treatment planning completed by multiple subspecialists at the CHARGE Center is necessary to correct or ameliorate his condition, while the alternative offered by Defendant is not. (Ex. 4, 5 & 6). If he does not get the treatment he needs, his providers agree that he W.B. will very likely have poor clinical outcomes including hospitalization and risk of developmental setback. (*Id.*)

As such, W.B. has established that he is suffering and will continue to suffer further irreparable harm resulting from Defendant's denial of a requested medical benefit to which he is entitled under EPSDT. *K.G.*, 839 F. Supp. 2d at 1278; *O.B.*,

170 F. Supp. 3d at 1196; *see also*, *Edmunds*, 417 F. Supp. 2d at 1342; *Mitson*, 670 F. Supp. at 1577; *Dodson*, 427 F. Supp. at 108; *Beltran*, 677 F.2d at 1322; *Newton-Nations*, 316 F. Supp. 2d at 888; *Benjamin H.* at 1999 WL 34783552 at 12; *Mass. Ass'n of Older Americans*, 700 F.2d at 753.

C. The injury to W.B. outweighs any injury to Defendant.

As set forth in Paragraph A of this motion, Defendant is obligated under federal law to provide W.B. with the out of state, specialty outpatient hospital services prescribed by his treating physician because the treatment is necessary to correct and ameliorate the effects of his CHARGE Syndrome. As set forth in Paragraph B of this motion, W.B., on the other hand, is a child who has been denied a service to which he is entitled under federal law and is essential to his health and safety. Denial of a Medicaid benefit, including an EPSDT benefit, has consistently been defined as irreparable harm. *Edmunds*, 417 F. Supp. 2d at 1342; *K.G.*, 839 F.Supp.2d at 1254; *O.B.*, 170 F. Supp. 3d at 1196.

In this case, the harm to W.B. far "outweighs whatever minimal harm a preliminary injunction might visit upon the State." *Lebron*, 820 F. Supp.2d at 1273, *aff'd*, *Lebron v. Sec'y, Fla. Dep't of Children & Families*, 710 F.3d 1202 (11th Cir. 2013). Defendant is designated under state law as the single state agency charged with the obligation of administering Medicaid benefits in compliance with federal law. Fla. Stat. § 409.902. As such, meeting its obligation to provide W.B. his

EPSDT benefits as required by law would not cause undue administrative burden or financial strain. *See K.G.*, 839 F. Supp. 2d at 1268 (finding that requiring the state to expend $16,500-$25,000 to pay for an EPSDT benefit where the child movant had established that he was substantially likely to succeed on the merits of his EPSDT claim did not pose a fiscal harm to the state that outweighed Plaintiff's irreparable harm from not receiving the benefit).

D. The public interest favors the entry of a preliminary injunction.

Granting a preliminary injunction will serve the public interest in upholding the law and enforcing the mandates of the Medicaid Act by preventing W.B. from suffering due to a lack of necessary care to ameliorate the medical complications resulting from his CHARGE syndrome. The grant of effective injunctive relief would be a strong affirmation of the public interest in the enforcement of laws to achieve the purpose for which Congress enacted them. *See K.G.* at 1280 (finding that "[t]he issuance of an injunction in the instant case would provide K.G. with necessary medical services furthering the state purpose of the Medicaid program).

IV. CONCLUSION

W.B. has, by substantial evidence and overwhelming and consistent authority, demonstrated that Defendant is violating his right to have his requested Medicaid services be evaluated under a standard that accords with federal law. W.B. has met his burden of showing that this is a proper case for injunctive relief

and respectfully requests that the Court enter a preliminary injunction prohibiting Defendant from applying the standard set forth in Fla. Admin. Code R. 59G-1.010 and, instead, evaluate W.B.'s request for care at the CHARGE Center pursuant to EPSDT, and to grant all other and further relief as may be just and proper under the facts and the law.

Respectfully submitted this 6th day of August 2021.

Plaintiffs by their Attorneys,

/s/ Katy DeBriere
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Counsel for Plaintiffs and Proposed Class Counsel

*Attorneys are appearing provisionally subject to approval to appear *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that on August 6, 2021, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. I further certify that I mailed the foregoing document and the notice of electronic filing by first-class mail to the following non-CM/ECF participants:

Simone Marstiller, Secretary
Agency for Health Care Administration
2727 Mahan Dr.
Tallahassee, FL 32308
(888) 419-3456

/s/ Katy DeBriere
Katherine DeBriere

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

W.B., by and through his father and legal guardian, David B., and A.W., by and through her mother and legal guardian, Brittany C., on behalf of themselves and all others similarly situated,

Plaintiffs,

v. Case No.:

SIMONE MARSTILLER, in her official capacity as Secretary for the FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,

Defendant.
_____/

EXHIBIT INDEX – W.B.'S MOTION FOR PRELIMINARY INJUNCTION

Exhibit Number	**Title of Exhibit**
Exhibit 1	Appendix
Exhibit 2	Plaintiff W.B. Medical Records
Exhibit 3	Declaration of David B.
Exhibit 4	Dr. Stephanie Carlin – Letter of Medical Necessity on behalf of Plaintiff W.B.
Exhibit 5	Dr. Gerardo Vazquez Garcia – Letter of Medical Necessity on behalf of Plaintiff W.B.
Exhibit 6	Dr. Andrew Simonsen – Letter of Medical Necessity on behalf of Plaintiff W.B.

Exhibit 7	CMS Plan Notice of Adverse Benefit Determination
Exhibit 8	Dr. Stephanie Carlin – expedited appeal of CMS Plan Notice of Adverse Benefit Determination
Exhibit 9	CMS Plan Notice of Appeal Plan Resolution
Exhibit 10	CMS Plan EPSDT Clinical Coverage Guidelines
Exhibit 11	AHCA EPSDT Memo
[redacted]	

Name: W[redacted] W B[redacted] | DOB: [redacted] | MRN: [redacted] | PCP: Stephanie A Carlin, DO

Medical and Family History (Westin)

MyUFHealth Medical History displays an overview of your medical history documented in your patient record within the UF Health network. If you have history items that are not documented below, please let your provider know at your next visit.

Medical History

Diagnosis	When
CHARGE syndrome	01/28/2020
Choanal atresia	01/28/2020
Anemia	01/28/2020
Coloboma of retina	01/28/2020
Congenital stenosis of pulmonary valve	01/02/2020
Facial palsy	01/29/2020
Gastrostomy tube dependent (CMS-HCC: 188)	01/28/2020
GERD (gastroesophageal reflux disease)	01/29/2020
Hypoparathyroidism	01/28/2020
Lagophthalmos of right eye	01/28/2020
Laryngomalacia	01/29/2020
Hearing loss	

Surgical History

Procedure	When
CHOANAL ATRESIA REPAIR	12/09/2019
GASTROSTOMY TUBE PLACEMENT	12/09/2019
CIRCUMCISION	12/09/2019
PERCUTANEOUS BALLOON VALVULOPLASTY	11/07/2019

Procedure	When
MYRINGOTOMY	10/21/2020
NASAL ENDOSCOPY	10/21/2020
LARYNGOSCOPY / BRONCHOSCOPY / ESOPHAGOSCOPY	10/21/2020

Family Medical History

Relationship	Health Issue	Comment
Other	Spinal Dysraphism	[redacted]
Mother	Anemia	
Maternal Grandmother	Hypertension	
Paternal Grandfather	Hypertension	
Maternal Grandfather	Diabetes	Type 2

Social History

You have no social history on file.

Family Status

Relationship	Status	Age at Death	Comment
Other			
Mother			
Maternal Grandmother			
Paternal Grandfather			
Maternal Grandfather			
Neg Hx			

DECLARATION OF DAVID B.

1. My name is David B.

2. I am forty-two years old and live in St. Augustine, Florida with my wife, Stacy B. and our three children: W.B. (almost two years old), J.D.B. (eight years old) and C.B. (six years old).

3. My son, W.B., is enrolled in Medicaid. His managed care plan is the Children's Medical Services Health Plan (the CMS Plan) administered by WellCare of Florida, Inc. This managed care plan is designed for Medicaid enrolled children who have special health care needs.

4. Within the first month of his life, W.B. was diagnosed with a rare genetic condition known as CHARGE Syndrome. It was identified early on because he presented with so many of the CHARGE markers including coloboma (his right eye has limited vision), a heart defect, choanal atresia (blocked nasal passages), misshapen ears, and problems swallowing.

5. Due to his CHARGE diagnosis, at birth, W.B. was admitted to the Newborn Intensive Care Unit for forty-three days. He was discharged right before December 25, 2019 but the, in the first week of January 2020, got very sick again. He was readmitted to the hospital and spent between two to three weeks in the Pediatric Intensive Care Unit and then another three weeks in non-intensive care before being discharged.

6. The CHARGE Syndrome impacts my son's medical and developmental condition. Some examples of how his development is impacted includes that he cannot swallow, he is mostly deaf, and he has low muscle tone (at almost two years old, he cannot sit up unassisted for longer than thirty seconds).

7. Since he is unable to swallow, my son uses a gastronomy tube for all of his nutrition.

8. My son also attends a Prescribed Pediatric Extended Care center Monday through Friday. At the PPEC, he receives nursing services, personal care, and developmental therapies including speech, occupational, and physical therapy.

9. Since birth, due to the medical and developmental complications of his diagnosis, my son has been followed by multiple specialists.

10. My son's pulmonologist is Dr. Gerardo A. Vazquez Garcia, M.D. who works at Nemours Children's Specialty Care clinic located in Jacksonville, Florida

11. W.B. also sees an Ear, Nose, and Throat (ENT) Specialist, Dr. Andrew R. Simonsen, D.O., who is in private practice in Jacksonville, Florida.

12. My son's pediatrician is Dr. Stephanie Carlin, D.O., who practices at UFHealth's Bower Lyman Center for Medically Complex Children.

13. The above-named physicians recommend that W.B. attend the CHARGE Center at Cincinnati Children's Hospital in Ohio.

14. They make this recommendation because W.B.'s diagnosis is so rare that only the providers at the CHARGE Center have the expertise necessary to evaluate and develop a plan of care that promises the best possible clinical outcomes for W.B. They have explained to me that without care at the CHARGE Center, my son will likely experience developmental setbacks and may continue to present with poor clinical outcomes, including continued hospitalizations.

15. From the months of January 2021 to April 2021, I had to take W.B. to the emergency room on five separate occasions due to respiratory distress. For all but one of these occasions, he was admitted to the hospital. The admissions ranged from two to three days each time.

16. To prevent ongoing hospitalizations, my son's physicians discussed whether to my son should undergo a tracheostomy. Fortunately, the physicians decided that, for now, the procedure is unnecessary. Again, however, they emphasized that the specialists at the CHARGE Center have the requisite expertise to determine the best method for avoiding further respiratory distress and subsequent hospitalizations.

17. W.B. also recently failed his swallow study. W.B.'s ENT, Dr. Simonsen, states that the experts at the CHARGE Center would best be able to evaluate W.B.'s swallowing and develop a treatment plan to correct the problem.

18. I speak regularly with the CHARGE Center about their willingness to provide care to W.B. They are always available to answer my emails and telephone calls with questions I have about his care locally. In response to our questions, the staff at the CHARGE Center have expressed the importance of W.B. being approved for their services. They have developed a preliminary evaluation and treatment plan he would undergo at the CHARGE Center if his insurance were to authorize the service.

19. As stated above, my wife and I have three young children. We also work full time. Although it would be a significant disruption to our daily lives, we are committed to traveling to Ohio so that my son can secure the care he needs to mitigate what has otherwise been a complex course of treatment in his short life.

20. We are also hopeful that, as represented by his physicians here in Florida and by the CHARGE Center, that the plan of care developed by the CHARGE Center and implemented locally will result in the best possible clinical outcomes for W.B.

21. It is incredibly frustrating to watch my young child be repeatedly hospitalized, be considered for invasive medical procedures, like a tracheostomy, without his providers, as amazing as they are, being certain about the medical necessity of the intervention, and otherwise try to manage and coordinate his care

when I know these concerns could be directly addressed by the expertise available only at the CHARGE Center.

22. For these reasons, I ask that the Court grant our request for preliminary relief on behalf of W.B. and order that the Agency for Health Care Administration evaluate Dr. Carlin's request for W.B. to attend the CHARGE Center under the correct standard; that is whether care at the CHARGE Center is necessary to correct or ameliorate the impact of CHARGE Syndrome on my son's health condition.

23. I greatly appreciate the Court's consideration of this matter.

Dated: 8/4/21

David B.

UF Health
UF Health Jacksonville
BOWER LYMAN CENTER FOR MEDICALLY COMPLEX CHILDREN
841 PRUDENTIAL DR, SUITE 900
JACKSONVILLE FL 32207-8373
Dept Phone: 904-202-8920
Dept Fax: 904-633-0921
UFHealthJax.org

* letter of medical necessity *

September 9, 2020

Patient: W[redacted] B[redacted]
Date of Birth: [redacted]

To Whom It May Concern:

I am writing on behalf of W[redacted] B[redacted] who attends the Bower Lyman Center for Medically Complex Children for his primary care.

W[redacted] is a 10 month old with a complex medical history of CHARGE Syndrome resulting in multiple congenital anomalies, choanal atresia (S/P repair), right facial palsy, laryngomalacia, coloboma, PV stenosis (S/P balloon valvulotomy), concerns for immunodeficiency, concern for hypoparathyroidism, dysphagia, GERD, and developmental delay. He is dependent on a gastrostomy tube for his nutritional needs.

W[redacted] has been referred to the CHARGE Center run by Cincinnati Children's Hospital. The CHARGE Center is the only center of its kind. It uses a multidisciplinary approach to providing care. The CHARGE Center is able to coordinate medical consultations between the many specialists involved in the care of a child with CHARGE Syndrome. Specialists working with the CHARGE Center include genetics, ophthalmology, cardiology, ENT, plastic surgery, and more.

The CHARGE Center can also provide guidance to local specialists involved in W[redacted] care. Their specialized knowledge of CHARGE syndrome will ensure that specialists involved have the latest recommendations for children with CHARGE Syndrome.

It is essential that the treatment of a child with CHARGE Syndrome be streamlined to avoid long-term developmental setbacks. The coordination of specialists that happens with the CHARGE Clinic also means that visits, testing, and evaluations are done in a sensible sequence, minimizing risk by consolidating anesthesia events and blood draws.

It is medically necessary that W[redacted] be evaluated and treated by the CHARGE Clinic which is an out of network provider. If there are any questions or concerns please feel free to contact our office.

Regards,

Stephanie Carlin, DO, FAAP
Bower Lyman Center for Medically Complex Children
Phone: (904) 202-8920
Fax: (904) 633-0931

Nemours Children's Specialty Care

Pulmonology Clinic
807 Children's Way
Jacksonville, FL 32207
904-697-3788
Nemours.org

July 6, 2021

To Whom It May Concern:

W[redacted] B[redacted] (DOB: [redacted]) is a medically complex 20-month-old male under my care for the treatment of ineffective airway clearance, chronic lung disease and pulmonary valve stenosis who requires supplemental oxygen and all of this within the context of CHARGE syndrome. CHARGE syndrome is an extremely complex rare genetic condition involving extensive medical and physical difficulties including swallowing and breathing problems caused by facial, throat, tracheal and/or esophageal malformations, as well as heart defects.

As evidence of his complexity, since birth W[redacted] has had four hospital admissions, three Emergency Department visits, and three admissions for observation all at Wolfson Children's Hospital. Caring for children born with CHARGE syndrome is complicated. Given the constellation of conditions present, he will likely continue to need extensive care from multiple specialists and therapists for the rest of his life.

As the pulmonologist on the aerodigestive team, I recommend that W[redacted] care be supervised by specialists knowledgeable about his condition. He should be evaluated without further delay at the CHARGE Center at Cincinnati Children's where they have expertise not available anywhere in Florida. Thank you for your attention to the needs of this child.

Sincerely,

Gerardo Vazquez Garcia, MD
Nemours Children's Specialty Care
Cystic Fibrosis Center
807 Children's Way
Jacksonville, FL 32207

Simonsen & Maddern Pediatric ENT
Otolaryngology · Head and Neck Surgery

Pediatric ENT

Andrew R. Simonsen, D.O. FAAP, FAOCO

Bruce R. Maddern, M.D. FACS, FAAP

Audrey O. Misel PA-C

Christina Geiger AuD, CCC-A

August 6, 2021

To Whom It May Concern:

W[redacted] B[redacted] is a medically complex 20-month-old male under mycare for the treatment of choanal atresia, chronic sinusitis, and dysphagia secondary to his underlying CHARGE syndrome. CHARGE syndrome is an extremely complex and rare genetic condition involving extensive medical and physical difficulties. These include swallowing and breathing problems caused by facial, throat, tracheal and/or esophageal malformations, visual and hearing problems, and heart defects.

As evidence of his complexity, since birth W[redacted] has required an extended NICU stay, multiple surgical interventions, a well as multiple hospital admissions and emergency department visits. Under my care he has undergone choanal atresia reconstruction along with multiple airway and hearing evaluations. His associated hearing loss will require lifelong hearing aid use and/or cochlear implantation. Caring for children born with CHARGE syndrome is complicated and given the constellation of conditions present he will require complex care from multiple specialists and therapists for the rest of his life.

As one of the Pediatric Otolaryngologists on the Craniofacial team, I recommend that W[redacted]'s care be supervised by specialists with expertise in his condition. As such, he would benefit from evaluation by the CHARGE Center at Cincinnati Children's where they may provide guidance and treatment options not available in Florida. Thank you for your attention to the needs of this child.

Sincerely,

Andrew Simonsen

Andrew Simonsen, DO, FAAP, FAOCO
Pediatric Otolaryngology-Head and Neck Surgery
Jacksonville, Florida

Children's Medical Services Health Plan
Operated by WellCare
PO Box 31370
Tampa, FL 33631-3370

PLAN ID: [redacted]

09/18/2020

W[redacted] B[redacted]
[redacted]
ST AUGUSTINE, FL [redacted]

010712282630

NOTICE OF ADVERSE BENEFIT DETERMINATION

Dear W[redacted] B[redacted] and/or DAVID B[redacted]:

Children's Medical Services Health Plan has reviewed a request for Outpatient Hospital Services and 2 Units/Visits, which we received on 09/11/2020. After our review, this service has been:

Denied as of 09/18/2020

We made our decision because:
We determined that your requested services are not medically necessary because the services do not meet the reason(s) checked below: (See Rule 59G-1.010)

* Must be able to be the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide.
* Must be furnished in a manner not primarily intended for convenience of the recipient, caretaker, or provider. (The convenience factor is not applied to the determination of the medically necessary level of private duty nursing (PDN) for children under the age of 21.)

The facts that we used to make our decision are:
On 7/22/2020, we received a request to authorize treatment for your child with an out of network provider, Dr. Monica Vielkind at Cincinnati Children's Hospital. We did not approve the request for authorization because out of network services are not a covered benefit when services are available within your plan. This service can be provided by one of the following in network providers:

1. Pediatric pulmonology

UF Health
2000 SW Archer Rd
Gainesville, FL 32608
352-265-8408

2. Pediatric Pulmonology
Nemours Children's Hospital
1717 Orange Ave S, #100
Orlando, FL
(407) 650-7715

Please contact your Primary Care Provider for assistance with a referral to an in network providers, and feel free to contact the WellCare Customer Service Department if you wish their assistance.
Criteria referenced: Children's Medical Services Health Plan Florida Medicaid Member Handbook, Section 10: Accessing Services

020712282630

You, or someone legally authorized to do so, can ask us for a complete copy of your child's file, including medical records, a copy of plan review criteria and guidelines, contract provisions, other documents, records, and other information relevant to the adverse benefit determination. These will be provided free of charge

You may request these documents by contacting: Children's Medical Services Health Plan toll-free at **1-866-799-5321** (TTY **711**) Monday–Friday, 8 a.m. to 7 p.m.

Right to Request a Plan Appeal

If you do not agree with this decision, you have the right to request a plan appeal from Children's Medical Services Health Plan. When you ask for a plan appeal, Children's Medical Services Health Plan has a different health care professional review the decision that was made.

How to Ask for a Plan Appeal:

You can ask for a plan appeal in writing or by calling us. Your child's case manager can help you with this. We must receive the request *within 60 days* of the date of this letter. (If you wish to continue your child's services until a final decision is made on your appeal, we must receive your request sooner. See the "How to Ask for your child's Services to Continue" section below for details.) Here is where to call or send your request:

Mail: Children's Medical Services
Attn: Appeals Department

Children's Medical Services Health Plan
Operated by WellCare
PO Box 31370
Tampa, FL 33631-3370

PLAN ID: [redacted]

09/14/2020

W[redacted] B[redacted]
[redacted]
ST AUGUSTINE, FL [redacted]

01079332980

NOTICE OF ADVERSE BENEFIT DETERMINATION

Dear W[redacted] B[redacted] and/or DAVID B[redacted]

Children's Medical Services Health Plan has reviewed a request for Outpatient Hospital Services and 10 Units/Visits, which we received on 09/11/2020. After our review, this service has been:

Denied as of 09/13/2020

We made our decision because:
We determined that your requested services are not medically necessary because the services do not meet the reason(s) checked below: (See Rule 59G-1.010)

* Must be able to be the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide.
* Must be furnished in a manner not primarily intended for convenience of the recipient, caretaker, or provider. (The convenience factor is not applied to the determination of the medically necessary level of private duty nursing (PDN) for children under the age of 21.)

The facts that we used to make our decision are:
On 9/11/2020, we received a request to authorize treatment for your child with an out of network provider, Dr. Catherine Hart at Cincinnati Children's Hospital. We did not approve the request for authorization because out of network services are not a covered benefit when services are available within your plan. This service can be provided by one of the following in network providers:

1. Pediatric ENT

UF Health
6201 W Newberry Rd
Gainesville, FL 32605
(352) 265-9465

2. Pediatric ENT
Nemours Children's Hospital
1717 Orange Ave S, #100
Orlando, FL
(407) 650-7000

Please contact your Primary Care Provider for assistance with a referral to an in network providers, and feel free to contact the WellCare Customer Service Department if you wish their assistance.
Criteria referenced: Children's Medical Services Health Plan Florida Medicaid Member Handbook, Section 10: Accessing Services

02079332980

You, or someone legally authorized to do so, can ask us for a complete copy of your child's file, including medical records, a copy of plan review criteria and guidelines, contract provisions, other documents, records, and other information relevant to the adverse benefit determination. These will be provided free of charge

You may request these documents by contacting: Children's Medical Services Health Plan toll-free at **1-866-799-5321** (TTY **711**) Monday–Friday, 8 a.m. to 7 p.m.

Right to Request a Plan Appeal

If you do not agree with this decision, you have the right to request a plan appeal from Children's Medical Services Health Plan. When you ask for a plan appeal, Children's Medical Services Health Plan has a different health care professional review the decision that was made.

How to Ask for a Plan Appeal:

You can ask for a plan appeal in writing or by calling us. Your child's case manager can help you with this. We must receive the request *within 60 days* of the date of this letter. (If you wish to continue your child's services until a final decision is made on your appeal, we must receive your request sooner. See the "How to Ask for your child's Services to Continue" section below for details.) Here is where to call or send your request:

Mail: Children's Medical Services
Attn: Appeals Department

[redacted]

Children's Medical Services Health Plan
Operated by WellCare
PO Box 31370
Tampa, FL 33631-3370

PLAN ID: [redacted]

09/18/2020

W[redacted] B[redacted]
[redacted]
ST AUGUSTINE, FL [redacted]

010712282640

NOTICE OF ADVERSE BENEFIT DETERMINATION

Dear W[redacted] B[redacted] and/or DAVID B[redacted]

Children's Medical Services Health Plan has reviewed a request for Consult and Treat and 2 Units/Visits, which we received on 09/11/2020. After our review, this service has been:

Denied as of 09/18/2020

We made our decision because:
We determined that your requested services are not medically necessary because the services do not meet the reason(s) checked below: (See Rule 59G-1.010)

* Must be able to be the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide.
* Must be furnished in a manner not primarily intended for convenience of the recipient, caretaker, or provider. (The convenience factor is not applied to the determination of the medically necessary level of private duty nursing (PDN) for children under the age of 21.)

The facts that we used to make our decision are:
On 9/11/2020, we received a request to authorize treatment for your child with an out of network provider, Dr. Putnam at Cincinnati Children's Hospital. We did not approve the request for authorization because out of network services are not a covered benefit when services are available within your plan. This service can be provided by one of the following in network providers:

1. Pediatric Gastroenterology

UF Health
2000 SW Archer Rd
Second floor
Gainesville, FL 32608
352-273-9350

2. Pediatric Gastroenterology
Nemours Children's Hospital
1717 Orange Ave S, #100
Orlando, FL
(407) 650-7715

Please contact your Primary Care Provider for assistance with a referral to an in network providers, and feel free to contact the WellCare Customer Service Department if you wish their assistance.
Criteria referenced: Children's Medical Services Health Plan Florida Medicaid Member Handbook, Section 10: Accessing Services

020712282540

You, or someone legally authorized to do so, can ask us for a complete copy of your child's file, including medical records, a copy of plan review criteria and guidelines, contract provisions, other documents, records, and other information relevant to the adverse benefit determination. These will be provided free of charge

You may request these documents by contacting: Children's Medical Services Health Plan toll-free at **1-866-799-5321** (TTY **711**) Monday–Friday, 8 a.m. to 7 p.m.

Right to Request a Plan Appeal

If you do not agree with this decision, you have the right to request a plan appeal from Children's Medical Services Health Plan. When you ask for a plan appeal, Children's Medical Services Health Plan has a different health care professional review the decision that was made.

How to Ask for a Plan Appeal:

You can ask for a plan appeal in writing or by calling us. Your child's case manager can help you with this. We must receive the request *within 60 days* of the date of this letter. (If you wish to continue your child's services until a final decision is made on your appeal, we must receive your request sooner. See the "How to Ask for your child's Services to Continue" section below for details.) Here is where to call or send your request:

Mail: Children's Medical Services

UFHealth
UF Health Jacksonville
BOWER LYMAN CENTER FOR MEDICALLY COMPLEX CHILDREN
841 PRUDENTIAL DR, SUITE 900
JACKSONVILLE FL 32207-8373
Dept Phone: 904-202-8920
Dept Fax: 904-633-0931
UFHealthJax.org

Expediated Appeal

Member: [redacted]
Member DOB: [redacted]
Member Medicaid ID: [redacted]
Denial Reference Numbers: PA-7979829; PA-7980409; PA-7979986

To CMS Appeals Department:

I am writing on behalf of W[redacted] B[redacted], who attends the Bower Lyman Center for Medically Complex Children for his primary care.

The prior authorization request for W[redacted] to be treated by the CHARGE Center run by Cincinnati Children's hospital has been denied. This letter is to serve as an appeal to the denials received for ENT (PA-7979986), GI (PA-7979829), and Pulmonology (PA-7980409).

Catherine Hart, MD (NPI 1346451655) has been identified by the CHARGE Center as the lead physician most appropriate for W[redacted] specific case. She is an ENT doctor specializing in CHARGE Syndrome. Dr. Hart will be working closely with the Pulmonologist, Dr. Monica Vielkind, and Gastroenterologist, Dr. Philip Putnam, who also specialize in CHARGE Syndrome.

The denial letters state that this patient was denied treatment due to "in network providers" being able to provide services. Unfortunately, there are no CHARGE centers in network that have a multidisciplinary team of providers who specialize in CHARGE. W[redacted] has had a complicated clinical course and his care would benefit from a multidisciplinary team approach to ensure that we are maximizing his care locally.

To review his clinical status- W[redacted] is a 10 month old with a complex medical history of CHARGE Syndrome resulting in multiple congenital anomalies, choanal atresia (S/P repair), right facial palsy, laryngomalacia, coloboma, PV stenosis (S/P balloon valvulotomy), concerns for immunodeficiency, concern for hypoparathyroidism, dysphagia, GERD, and developmental delay. He is dependent on a gastrostomy tube for his nutritional needs.

Based on the medical history and ongoing issues outlined above, please reconsider the denial decision for this patient as it would be detrimental to W[redacted] health for him to be excluded from the CHARGE Center. Please feel free to contact my office should you have further questions or concerns regarding my request for approval.

Regards,

Stephanie Carlin, DO, FAAP Bower Lyman Center for Medically Complex Children
904-383-1864

Patient Care Research Education

P.O. Box 31368
Tampa, FL 33631-3365

PLAN ID: [redacted]

November 13, 2020

Kelsey Bell/ Dr. Stephanie Carlin
841 Prudential Dr. Suite 900
Jacksonville, FL 32207

Re: W[redacted] B[redacted]
ID#: [redacted]
File #: [redacted]
Request: Treatment With OON Provider Dr. Putnam
Date of Service: Pending

NOTICE OF PLAN APPEAL RESOLUTION

Dear Parent/Legal Guardian of W[redacted] B[redacted]

On 10/15/2020 we received your timely plan appeal request regarding Children's Medical Services Health Plan Notice of Adverse Benefit Determination dated 9/18/2020, NABD Number ACME-16-000156 denying the service provided to you.

The request has been reviewed. The review was completed by a licensed doctor. The doctor was not a part of the first review or the findings from that review.

The Medical Director involved is Board Certified MD with a specialty in Pediatrics.

On 11/11/2020, after consideration of the information you provided to Childern's Medical Services Health Plan in support of your plan appeal, Children's Medical Services Health Plan hereby Denies your plan appeal. As a result, you will not receive service, effective 11/11/2020.

The facts that we used to make our decision are: We have doctor's who can see and manage your condition. The reasons for this decision are based on a set of standards. This included Wellcare Health Plans, Inc. Find A Provider Website-Member Benefit.

You, or someone legally authorized to do so, can ask us for a complete copy of your file, including medical records, a copy of plan review criteria and guidelines, contract provisions, other documents, records, and other information considered during the plan appeal process. These will be provided free of charge.

Right to Request a State Medicaid Fair Hearing

If you do not agree with this decision, you have the right to request a Medicaid fair hearing from the state. When you ask for a fair hearing, a hearing officer who works for the state reviews the decision made during the plan appeal.

How to Ask for a Fair Hearing:
You may ask for a fair hearing any time up to 120 days after you get this Notice of Plan Appeal Resolution. Your child's case manager can help you with this, if he/she has one.

You may ask for a fair hearing by calling or writing to:

Agency for Health Care Administration
Medicaid Hearing Unit
P.O. Box 60127
Ft. Myers, FL 33906

(877) 254-1055 *(toll-free)*
239-338-2642 *(fax)*
MedicaidHearingUnit@ahca.myflorida.com

Your written request for a Medicaid fair hearing must include the following information:

- Your child's name
- Your child's member number
- Your child's Medicaid ID number
- A phone number where we can reach you or your authorized representative

You may also include the following information if you have it:

- Why you think we should change the decision
- Any medical information to support the request
- Who you would like to help with your fair hearing

After getting your fair hearing request, the Agency for Health Care Administration (Agency) will tell you in writing that they got your fair hearing request.

How to Ask for Your Child's Services to Continue During a Fair Hearing:

If your child was receiving services during your plan appeal, file the request for your child's services to continue with the Agency **no later than 10 days** from the date on this Notice of Plan Appeal Resolution OR on or before the first day that your child's services are scheduled to be reduced, suspended, or terminated, *whichever is later.*

If your child's services are continued and our decision is upheld in a fair hearing, we may ask that you pay for the cost of those services. We will not take away your child's

Medicaid benefits. We cannot ask your family or legal representative to pay for the services.

If you have questions, call us at **1-866-799-5321** (TTY **711**) Monday–Friday 8 a.m. to 7 p.m.

For more information on your rights, review the Grievance and Appeal section in your child's Member Handbook. It can be found online at: www.wellcare.com/florida

Sincerely,

Melissa Thomas, MD

Corporate Medical Director
Children's Medical Services Health Plan

Cc: Parent/Legal Guardian of W[redacted] B[redacted]

The Children's Medical Services Health Plan has partnered with WellCare of Florida, Inc. (WellCare) to provide managed care services to our members. WellCare is a licensed Florida health plan.

Children's Medical Services Health Plan

Discrimination is Against the Law

Children's Medical Services Health Plan, complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Children's Medical Services Health Plan does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Children's Medical Services Health Plan:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, Braille, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact Children's Medical Services Health Plan at 1-866-799-5321 (TTY: 711), Monday–Friday from 8 a.m. to 7 p.m., for help or you can ask Customer Service to put you in touch with a Civil Rights Coordinator who works for Children's Medical Services Health Plan.

If you believe that Children's Medical Services Health Plan has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Children's Medical Services Health Plan, Grievance Department, P.O. Box 31384, Tampa, FL 33631-3384; Telephone 1-866-530-9491; TTY number 711; Fax: 1-866-388-1769; OperationalGrievance@wellcare.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Children's Medical Services Health Plan Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 1-800-537-7697 (TDD).

Complaint forms are available at https://www.hhs.gov/ocr/office/file/index.html.

Staywell of Florida

Children's Medical Services Health Plan (CMS Health Plan)

Florida Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Therapy

Policy Number: HS-260

Original Effective Date: 5/26/2017

Revised Date(s): 4/5/2018, 4/4/2019; 4/16/2020

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Early and Periodic, Screening, Diagnosis and Treatment (EPSDT)

EPSDT provides a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children and adolescents under the age of 21 years. The EPSDT benefit for this population is designed to assure that children receive early detection and care in order to address health problems as soon as early as possible. Additional information is provided below regarding EPSDT:[1]

- **IFSP.** For children up to 3 years old and enrolled in the Early Steps Program - if there is an IFSP, providers are asked to provide a copy if available.
- **Standardized test results** will NOT be used as the sole determinant as to the medical necessity of the requested services. Standard tests will not be required when such tests are inappropriate due to the condition of the member or when no such standardized test is generally available to evaluate the condition for which therapy services are requested.
- **Group Speech Therapy.** To be reimbursed by Medicaid, a group speech therapy session is limited to six children. All the children do not have to be Medicaid members. The group must receive a minimum of 30 minutes of therapy. Medicaid will not reimburse for both group and individual speech therapy sessions for a member on the same day.
- **Other Services and Goods.** The fact that a provider has prescribed, recommended or approved medical or allied care, goods or services do not in itself make such care, goods or services medically necessary or a covered service.
- **Duplication of Services.** Medicaid reimburses for services that are determined medically necessary and do not duplicate another provider's service.
- **Travel.** Reimbursement is NOT allowed as part of any early intervention session.

Original Effective Date: 5/26/2017 - Revised: 4/5/2018, 4/4/2019, 4/16/2020
PRO_55310E Internal/State Approved 07272020 FL0PROWEB55310E_0000

- **Reimbursement**. Only one type of early intervention session per day, per child is allowed. A session cannot be split between providers, nor can more than one type of provider conduct a session in a given day for the same child.

POSITION STATEMENT

Applicable To:

- ☑ Medicaid – Florida
- ☑ Children's Medical Services Health Plan (CHIP)

For all other markets, refer to *Pediatric Skilled Therapy Services for Developmental Delay (HS-201).*

NOTE: Refer authorizations to vendor, as applicable.

Early and Periodic, Screening, Diagnosis and Treatment (EPSDT) [1]

EPSDT services **are a covered benefit** for Members ≤ age 21 years when the treatment or procedure fits within the following categories of Medicaid-covered services if it is necessary to "correct or ameliorate" defects and physical and mental illnesses or conditions. For example, services must be:

- Needed to protect life, prevent significant illness or disability, or alleviate severe pain; **AND/OR**
- Individualized, specific, consistent with symptoms or diagnosis of illness or injury and not be in excess of the Member's needs; **AND/OR**
- In alignment with accepted medical standards and not be experimental or investigational; **AND/OR**
- The level of service that can be safely furnished and for which no equally effective and more conservative or less costly treatment is available in the State of Florida; **AND/OR**
- Furnished in a manner not primarily intended for convenience of the recipient, caretaker, or provider.

Services include, but are not limited to:

- Behavioral Health Overlay Services
- Child Health Check-Up Services
- Chiropractic Services
- Dental Services
- Durable Medical Equipment/ Medical Supply Services
- Early Intervention Services
- Hearing Services
- Home Health Services
- Hospital Services, including Psychiatric Services
- Nursing Facility Services
- Optometric Services
- Physician Services
- Podiatry Services
- Prescribed Drug Services
- Targeted Case Management Services

NOTE: Medicaid must provide any other medical or remedial care, even if the agency does not otherwise provide for these services or provides for them in a lesser amount, duration, or scope.[1]

Also included under EPSDT are diagnostic services, treatment, equipment, supplies, and other measures. As such, services for recipients ≤ age 21 years exceeding the coverage described within Florida Medicaid policy or the associated fee schedule may be approved, if medically necessary.

Prior Authorization

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Prior authorization is required in order to receive reimbursement for special services that meet one or more of the following conditions.

- Service is not listed in the service-specific Medicaid Coverage and Limitations Handbook as a covered service; **AND/OR**
- Service is not included in the applicable fee schedule; **AND/OR**
- Service is described in the service-specific handbook as an "excluded service"; **AND/OR**
- The amount, frequency, or duration of the service exceeds the limitations specified in the service-specific handbook or the fee schedule.

The following services are carved out of managed care and available to members based upon the eligibility criteria for each service:[1]

- Home and Community-Based Waiver services (excluding services provided under the LTC program)
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) services
- Nursing facility services (for children under the age of 18 years)
- Medical Foster Care services
- Prescribed Pediatric Extended Care (PPEC) services
- Newborn hearing screening
- Early intervention services
- Applied behavior analysis (for children diagnosed with autism or autism spectrum disorders)
- Program for All-inclusive Care for Children (PACC)

WellCare is responsible for arranging, coordinating, and referring the enrollee to the appropriate program to meet the Member's needs. WellCare is required to provide basic information to assist the Member in understanding the type of service available and, when appropriate, arrange an appointment for the enrollee to obtain the service. For more information, refer to the specific coverage policies found here.[2]

Physical and Occupational Therapy

Exclusions [3,4]

The following services related to PT and OT **are not covered** when any of the following apply:

- The service does not meet the medical necessity criteria listed below; **OR**
- The recipient does not meet the eligibility requirements listed below; **OR**
- The service unnecessarily duplicates another provider's service.

In addition, Florida Medicaid does not cover the following as part of the service benefit:

- Developing and updating the plan of care (POC)
- Mileage and travel expenses
- Multiple AAC fitting, adjustment, and training visits on the same day
- Securing, installing, or maintaining therapy equipment
- Services not listed on the fee schedule
- Telephone communications with recipients, their representatives, caregivers, and other
- providers, except for services rendered in accordance with the Florida Medicaid
- telemedicine policy
- Time spent supervising assistants and students
- Treatment visits provided on the same day as an evaluation service

Coverage [3,4]

Physical and occupational therapy **is a covered benefit** when followed in accordance with the applicable fee schedule(s) set by Florida Medicaid, or as specified in this policy:

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- Wheelchair evaluations:
  - One initial wheelchair evaluation every five years, per recipient
  - One follow-up wheelchair evaluation including adjustments and fittings when the wheelchair is delivered
  - One follow-up wheelchair evaluation including adjustments and fittings six months after the wheelchair has been delivered

- Services for recipients under the age of 21 years:
  - One initial therapy evaluation per year, per recipient
  - One therapy re-evaluation every five months, per recipient
  - Up to 14 therapy treatment units per week (Sunday-Saturday), per recipient (max of 4 units per day)
  - Up to two casting and strapping applications per day, per recipient

Speech Therapy (ST)

Additional information for ST may be found in *Augmentative Alternative Communication Devices for Developmental Delay (E/I): HS-205.*

Exclusions [5]

Speech therapy related treatments for stuttering **are not medically necessary** and not a covered benefit when:
- The service does not meet the medical necessity criteria listed below; **OR**
- The recipient does not meet the eligibility requirements listed below; **OR**
- The service unnecessarily duplicates another provider's service.

In addition, Florida Medicaid does not cover the following as part of the service benefit:
- Developing and updating the plan of care (POC)
- Mileage and travel expenses
- Multiple AAC fitting, adjustment, and training visits on the same day
- Securing, installing, or maintaining therapy equipment
- Services not listed on the fee schedule
- Telephone communications with recipients, their representatives, caregivers, and other
- providers, except for services rendered in accordance with the Florida Medicaid
- telemedicine policy
- Time spent supervising assistants and students
- Treatment visits provided on the same day as an evaluation service

Coverage

Speech Therapy **is a covered benefit** when followed in accordance with the applicable fee schedule(s), or as specified in this policy: [5]
- One initial AAC evaluation every five years, per recipient
- For recipients under the age of 21 years:
  - One initial speech-language pathology evaluation per year, per recipient
  - One speech-language re-evaluation every five months, per recipient
  - Up to 14 therapy treatment units per week (Sunday-Saturday), per recipient (max of 4 units per day)
    - Group therapy must be at least 30 minutes in duration, and may include no more than six participants (the group may include non-Medicaid recipients)
  - One follow-up AAC evaluation upon delivery of the device, per recipient
  - Up to eight 30-minute AAC fitting, adjustment, and training sessions per year, per recipient
  - Up to two AAC reevaluations per year, per recipient with an AAC device

For initial and ongoing ST services, the following elements should be included in the medical necessity review:
In addition, criteria is met and visits are approved according to the following scores:

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- **Mild (-1 to -1.5 standard deviation from the mean [or a score of 85 to 78]).** *Approval of 1 visit weekly up to 26 weeks.*
- **Moderate (-1.5 to -2 standard deviation from the mean [or a score of 77 to 71]).** *Approval of 2 visits weekly up to 26 weeks.*
- **Severe and Profound (>2 standard deviation from the mean [or a score of 70 or below]).** *Approval of 3 visits weekly up to 26 weeks.*

In addition, members who have been receiving speech therapy services for ≥18 months must undergo a secondary medical necessity review by a medical director.

Augmentative and Alternative Communication (AAC)

AACs are designed to allow individuals the capability to communicate. As defined by the American Speech-Language Hearing Association (ASHA), an AAC attempts to compensate for the impairment and disability patterns of individuals with severe, expressive communication disorders, i.e., individuals with severe speech-language and writing impairments. Dedicated systems are designed specifically for a disabled population. Non-dedicated systems are commercially available devices such as laptop computers with special software.

AAC evaluations, fittings, adjustments and training are reimbursed through the Medicaid therapy services program for members under the age of 21. AACs are reimbursed through the Florida Medicaid Durable Medical Equipment and Medical Supply Services Program. For coverage for an AAC system, the member must:

- Be unable to communicate basic needs without the use of an AAC; **AND**
- Have the physical, cognitive and language abilities necessary to use the AAC system.

Medicaid reimburses home health agencies for OT, PT, and SLP services through their home health agency provider numbers. Medicaid **does not reimburse** home health agencies for respiratory therapy services through their home health agency provider number. Home health agencies may enroll as group therapy providers with a specialty in respiratory therapy. The home health agency must have at least two licensed registered respiratory therapists in the group that are enrolled as individual providers in Medicaid.

Additional Guidance for PT, OT, and ST

Children with a developmental delay (all ages) have development delayed in **one or more** of the following domains:

- Cognition;
- Physical or motor;
- Sensory (including vision and hearing);
- Communication;
- Social;
- Emotional;
- Adaptive development

Services for children with chronic conditions **are considered medically necessary** when the following are met in cases where initial **OR** continuing authorization requests are not accompanied by case history records:

- Therapy services must be prescribed by a primary care physician (PCP), advanced registered nurse practitioner (ARNP), physician assistant (PA), physical therapist (PT), occupational therapist (OT), respiratory therapist (RT), speech-language pathologist (SLP) or other designated physician specialist**. Prescription for services must include the following:
  - Member's diagnosis; **AND**
  - Specific type of evaluation requested or the specific type of service; **AND**
  - Duration and frequency of the therapy treatment period; **AND**

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- Physician's MediPass authorization number, if applicable.

- For ongoing services, a multidisciplinary evaluation and Plan of Care (POC) must:
  - Be evaluated and signed by the treating therapist and child's PCP; **AND**
  - Outline the current level of function, the appropriate services, frequencies and goals for each therapy modality for the child; **AND**
  - Be current within the six months prior to the request*; **AND**
  - For members in Early Steps, the level of function should be expressed as a percentile rank on a standard functional assessment **OR** standard deviation from the mean on a standard functional assessment*

NOTE: Please see Definitions section for description of Plan of Care.

* **The primary care provider must review the member's renewed plan of care every one to six months** depending on the authorization period for which the services were approved. If the services continue to be medically necessary, the primary care provider can prescribe the reauthorization of services. The plan of care, with the primary care provider's, ARNP's or PA designee's, or designated physician specialist's signature authorizing the continuation of services, must be received prior to beginning services for the next authorization period.

** Authorizations (including those by a vendor contracted by WellCare) must follow a specialty-specific review process for reviewing pediatric therapy cases. For example, therapy cases must be reviewed by the same specialty (e.g., OT cases are to be reviewed by and OT, PT cases are to be reviewed by PT except in cases when a Physiatrist (PM&R) can review such cases. In Florida, initial therapy evaluations generally can only be initiated by a PT or OT or SLP as part of their scope of practice. **Medicaid does not reimburse for evaluations performed by therapy assistants.** See Reference section for applicable Florida Statutes.

Evaluations determine the member's level of function and competencies through therapeutic observation and testing; to develop baseline data to identify the need for early intervention; and to address the member's functional abilities, capabilities, activities performance, deficits and limitations. Additional information may be required:

- Tests may be standardized or may be composed of the professionally acceptable techniques.

Criteria for Services [1]

Services must meet the following criteria:

- Provided by:
  - Licensed physical, occupational and registered respiratory therapists;
  - Licensed speech-language pathologists and provisionally licensed speech-language pathologists; and
  - Home health agencies that employ or contract with licensed physical and occupational therapists, licensed speech-language pathologists, and provisionally licensed speech-language pathologists.
- Be individualized, specific, consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the member's needs;
- Cannot be experimental or investigational;
- Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
- Be furnished in a manner not primarily intended for the convenience of the member, the member's caretaker, or the provider.

Note: Medicaid does not reimburse for evaluations performed by therapy assistants.

Services **can be provided in the member's home or other community setting,** such as schools, prescribed pediatric extended care centers or day care centers. Services for children ages 4 and up may be performed in the home setting if the member is classified as homebound.

Services **can also be provided in a nursing facility, intermediate care facility for the developmentally disabled (ICF/DD), and an inpatient and outpatient hospital.** Payment for these services is included in the facility's per diem. The therapist cannot be reimbursed directly by fee-for-service for services provided in these locations.

Establishing Developmental Delay

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The following criteria must be used **to establish developmental delay** using appropriate standardized instruments:

- For children up to 3 years old and enrolled in the Early Steps Program:
  - Score that equals or exceeds 1.5 standard deviations below the mean in at least one of the identified domains**; **OR**
  - A twenty-five (25) percent delay or greater on measures yielding scores in months in at least one of the identified domains**

CODING

Covered CPT®* Codes (For Speech-Language Pathology Services)
***See handbook for modifiers that apply. This list may not be all inclusive.**
92521 Evaluation of speech fluency (eg, stuttering, cluttering)
92522 Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);
92523 Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)
92524 Behavioral and qualitative analysis of voice and resonance
92507 Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508 Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals
92597 Evaluation for use and/or fitting of voice prosthetic device to supplement oral speech
92609 Therapeutic services for the use of speech-generating device, including programming and modification

Covered CPT Codes (For Occupational Therapy Services)
***See handbook for modifiers that apply. This list may not be all inclusive.**
29799 Unlisted procedure, casting or strapping
92597 Evaluation for use and/or fitting of voice prosthetic device to supplement oral speech
97165 Occupational therapy evaluation, low complexity, requiring these components…
97166 Occupational therapy evaluation, moderate complexity, requiring these components…
97167 Occupational therapy evaluation, high complexity, requiring these components…
97168 Re-evaluation of occupational therapy established plan of care, requiring these components…
97530 Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
97542 Wheelchair management (eg, assessment, fitting, training), each 15 minutes

Covered HCPCS Codes (for Behavioral Health Overlay Services)
***See handbook for modifiers that apply. This list may not be all inclusive.**
H0001 Alcohol and/or drug assessment
H0019 Behavioral health; long-term residential (nonmedical, nonacute care in a residential treatment program where stay is typically longer than 30 days), without room and board, per diem
H0020 Alcohol and/or drug services; methadone administration and/or service (provision of the drug by a licensed program)
H0031 Mental health assessment, by nonphysician
H0032 Mental health service plan development by nonphysician
H0046 Mental health services, not otherwise specified
H0047 Alcohol and/or other drug abuse services, not otherwise specified
H2000 Comprehensive multidisciplinary evaluation
H2010 Comprehensive medication services, per 15 minutes
H2012 Behavioral health day treatment, per hour
H2017 Psychosocial rehabilitation services, per 15 minutes
H2019 Therapeutic behavioral services, per 15 minutes
H2030 Mental health clubhouse services, per 15 minutes
T1007 Alcohol and/or substance abuse services, treatment plan development and/or modification

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T1015 Clinic visit/encounter, all-inclusive
T1023 Screening to determine the appropriateness of consideration of an individual for participation in a specified program, project or treatment protocol, per encounter
S5145 Foster care, therapeutic, child; per diem

Covered HCPCS Codes (For CHILD HEALTH SERVICES TARGETED CASE MANAGEMENT)
***See handbook for modifiers that apply. This list may not be all inclusive.**
T1017 Targeted case management, each 15 minutes

Covered HCPCS Codes (For Dental) ***This list may not be all inclusive.**
D0120 Periodic oral evaluation
D0140 Limited oral evaluation
D0150 Comprehensive oral evaluation
D0190 Screening of a patient
D0191 Assessment of a patient
99188 Application of topical fluoride varnish by a physician or other qualified health care professional
D1206 Topical application of fluoride varnish
D1208 Topical application of fluoride excluding varnish

Covered HCPCS Codes (For Early Intervention Services).
***See handbook for modifiers that apply. This list may not be all inclusive.**
T1023 Screening to determine the appropriateness of consideration of an individual for participation in a specified program, project or treatment protocol, per encounter
T1024 Evaluation and treatment by an integrated, specialty team contracted to provide coordinated care to multiple or severely handicapped children, per encounter
T1027 Family training and counseling for child development, per 15 minutes

Covered HCPCS Codes (For Hearing Services)
***See handbook for modifiers that apply. This list may not be all inclusive.**
69210 Removal impacted cerumen requiring instrumentation, unilateral
92541 Spontaneous nystagmus test, including gaze and fixation nystagmus, with recording
92542 Positional nystagmus test, minimum of 4 positions, with recording
92544 Optokinetic nystagmus test, bidirectional, foveal or peripheral stimulation, with recording
92545 Oscillating tracking test, with recording
92546 Sinusoidal vertical axis rotational testing
92547 Use of vertical electrodes (List separately in addition to code for primary procedure)
92550 Tympanometry and reflex threshold measurements
92552 Pure tone audiometry (threshold); air only
92553 Pure tone audiometry (threshold); air and bone
92555 Speech audiometry threshold;
92556 Speech audiometry threshold; with speech recognition
92557 Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)
92567 Tympanometry (impedance testing)
92568 Acoustic reflex testing, threshold
92570 Acoustic immittance testing, includes tympanometry (impedance testing), acoustic reflex threshold testing, and acoustic reflex decay testing
92571 Filtered speech test
92572 Staggered spondaic word test
92579 Visual reinforcement audiometry (VRA)
92582 Conditioning play audiometry
92585 Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive
92586 Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited

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92587 Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3-6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report
92588 Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report
92601 Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602 Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603 Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604 Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming
92620 Evaluation of central auditory function, with report; initial 60 minutes
92621 Evaluation of central auditory function, with report; each additional 15 minutes (List separately in addition to code for primary procedure)
92626 Evaluation of auditory rehabilitation status; first hour
92627 Evaluation of auditory rehabilitation status; each additional 15 minutes (List separately in addition to code for primary procedure)
92630 Auditory rehabilitation; prelingual hearing loss
92633 Auditory rehabilitation; postlingual hearing loss
92640 Diagnostic analysis with programming of auditory brainstem implant, per hour
92700 Unlisted otorhinolaryngological service or procedure
L7510 Repair of prosthetic device, repair or replace minor parts
L8614 Cochlear device, includes all internal and external components
L8615 Headset/headpiece for use with cochlear implant device, replacement
L8616 Microphone for use with cochlear implant device, replacement
L8617 Transmitting coil for use with cochlear implant device, replacement
L8618 Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
L8619 Cochlear implant, external speech processor and controller, integrated system, replacement
L8623 Lithium ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each
L8624 Lithium ion battery for use with cochlear implant device or auditory osseointegrated device speech processor, ear level, replacement, each
L8627 Cochlear implant, external speech processor, component, replacement
L8628 Cochlear implant, external controller component, replacement
L8629 Transmitting coil and cable, integrated, for use with cochlear implant device, replacement
L8691 Auditory osseointegrated device, external sound processor, replacement
L8692 Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
V5010 Assessment for hearing aid
V5014 Repair/modification of a hearing aid
V5050 Hearing aid, monaural, in the ear
V5060 Hearing aid, monaural, behind the ear
V5090 Dispensing fee, unspecified hearing aid
V5130 Binaural, in the ear
V5140 Binaural, behind the ear
V5160 Dispensing fee, binaural
V5180 Hearing aid, CROS, behind the ear
V5200 Dispensing fee, CROS
V5220 Hearing aid, BICROS, behind the ear
V5240 Dispensing fee, BICROS
V5264 Ear mold/insert, not disposable, any type
V5299 Hearing service, miscellaneous

Covered HCPCS Codes (For Home Health Services)
***See handbook for modifiers that apply. This list may not be all inclusive.**

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T1021 Home health aide or certified nurse assistant, per visit
T1030 Nursing care, in the home, by registered nurse, per diem
T1031 Nursing care, in the home, by licensed practical nurse, per diem

Covered HCPCS Codes (For Child Health Services Targeted Case Management, Mental Health Targeted Case Management, and Targeted Case Management for Children at Risk of Abuse and Neglect Handbooks)
***See handbook for modifiers that apply. This list may not be all inclusive.**
T1017 Targeted case management, each 15 minutes
T2023 Targeted case management; per month

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Early and Periodic, Screening, Diagnosis and Treatment (EPSDT) Requirements in the Managed Medical Assistance Program. Agency for Health Care Administration Web site. https://ahca.myflorida.com/medicaid/statewide_mc/pdf/EPSDT_Overview_FAQs_2017-07-17.pdf. Published June 6, 2016. Accessed April 10, 2020.
2. Florida State Medicaid Manuals. Agency for Health Care Administration Web site. http://portal.flmmis.com/FLPublic/Provider_ProviderServices/Provider_ProviderSupport/Provider_ProviderSupport_ProviderHandbooks/tabId/53/Default.aspx. Accessed April 10, 2020.
3. Physical Therapy Services Coverage Policy. Agency for Health Care Administration Web site. http://ahca.myflorida.com/medicaid/review/Specific/59G_4-320_Physical_Therapy_Services.pdf Published October 2016. Accessed April 10, 2020.
4. Occupational Therapy Services Coverage Policy. Agency for Health Care Administration Web site. http://ahca.myflorida.com/medicaid/review/Specific/59G_4-318_Occupational_Therapy_Services.pdf Published October 2016. Accessed April 10, 2020.
5. Speech-Language Pathology Services Coverage Policy. Agency for Health Care Administration Web site. http://ahca.myflorida.com/medicaid/review/Specific/59G_4-324_Speech_Language_Therapy_Services.pdf Published October 2016. Accessed April 10, 2020.
6. Florida Medicaid Behavioral Health Overlay Services, Service Specific Policies. Agency for Health Care Administration Web Site. http://ahca.myflorida.com/medicaid/review/specific_policy.shtml. Accessed April 10, 2020.
7. Florida Medicaid Child Health Services Targeted Case Management Service-Specific Policies. Agency for Health Care Administration Web Site. http://ahca.myflorida.com/medicaid/review/specific_policy.shtml. Accessed April 10, 2020.
8. Florida Medicaid Dental Services, Service Specific Policies. Agency for Health Care Administration Web Site. http://ahca.myflorida.com/medicaid/review/specific_policy.shtml. Accessed April 10, 2020.
9. Florida Medicaid Early Intervention Services Coverage and Limitations Handbook. Agency for Health Care Administration Web Site. http://ahca.myflorida.com/medicaid/review/Specific/CL_07_070801_EIS_ver1_3.pdf. Accessed April 10, 2020.
10. Florida Medicaid, Provider Reimbursement Schedules and Billing Codes Web Site. Hearing Services Fee Schedule. http://ahca.myflorida.com/medicaid/review/fee_schedules.shtml. Accessed April 10, 2020.
11. Florida Medicaid Home Health Visit Services Fee Schedule. http://ahca.myflorida.com/medicaid/review/Reimbursement/Home_Health_Visit_Services_Fee_Schedule.pdf. Accessed April 10, 2020.
12. Florida Medicaid Mental Health Targeted Case Management Coverage and Limitations Handbook. Service-Specific Policy web Site. https://ahca.myflorida.com/medicaid/review/Specific/CL_07_070601_MH_Case_Mgmt_ver2_2.pdf. Accessed April 10, 2020.
13. Florida Medicaid Targeted Case Management for Children at Risk of Abuse and Neglect handbook from Service-Specific Web Site. https://ahca.myflorida.com/Medicaid/Policy_and_Quality/Policy/behavioral_health_coverage/bhfu/index.shtml. Accessed April 10, 2020.
14. Florida Medicaid Speech-Language Pathology Services Fee Schedule. http://ahca.myflorida.com/medicaid/review/Reimbursement/SLP_Fee_Schedule.pdf Accessed April 10, 2020.
15. Florida Medicaid Occupational Therapy Services Fee Schedule. http://ahca.myflorida.com/medicaid/review/Reimbursement/2017_01_01_Occupational_Therapy_Fee_Schedule.pdf. Accessed April 10, 2020.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
4/16/2020, 4/4/20419, 4/5/2018	• Approved by MPC. No changes.
5/26/2017	• Approved by MPC. New.

RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

MEMORANDUM

DATE: April 25, 2017

TO: Stuart Williams, General Counsel, Agency for Health Care Administration

FROM: Tracy George, Chief Appellate Counsel, Agency for Health Care Administration[1]

SUBJECT: Summary Memorandum: Medical Necessity as a Limitation on Medicaid Services, Including EPSDT

Introduction

The purposes of this Summary Memorandum are to: a) identify the federal law authorizing states to limit Medicaid services, including early and periodic screening, diagnosis, and treatment ("EPSDT"), based on medical necessity; b) explain how Florida Medicaid utilizes medical necessity limitations in its case-by-case services determinations; and c) identify guiding principles in the federal case law that inform the Florida Medicaid medical necessity inquiry.

A. Overview of the Medicaid Program.

1. The State and Federal Medicaid Agencies.

In Florida, AHCA is the "single state agency" responsible for administering the Medicaid Program and for ensuring compliance with state and federal Medicaid laws and rules. 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10(b); §§ 409.811(2), 409.8132, 409.818(3), 409.902, Fla. Stat. The Federal Medicaid agency is the Department of Health and Human Service, Centers for

[1] Tracy George drafted the original memorandum, issued on August 5, 2014. Subsequent updates were provided by Kevin Dewar, Assistant General Counsel, Agency for Health Care Administration.

Medicaid and Medicare Services ("CMS"). 5 C.F.R. § 5501.102(a)(6); 42 C.F.R. § 400.200. *See, generally,* 42 C.F.R. ch. IV.C.

2. The Medicaid State Plan and Services.

Medicaid is a cooperative federal-state program, established pursuant to Title XIX of the Social Security Act, for funding medical services for the needy. 42 U.S.C. § 1396, *et seq.* A state that chooses to participate in Medicaid submits a plan, known as the "Medicaid State Plan," to CMS. *Harris v. James*, 127 F.3d 993, 996 (11th Cir. 1997). If CMS approves the Medicaid State Plan, the state and federal governments jointly pay for medical services in accordance with its terms. *Id.*

The twenty-nine (29) services that can be provided under a Medicaid State Plan are listed in 42 U.S.C. §§ 1396d(a)(1) through (a)(29). Coverage of eight (8) of these services, including early and periodic screening, diagnosis, and treatment ("EPSDT") services, is mandatory, and the services must be provided by every Medicaid-participating state. Because coverage of the remaining twenty-one (21) services is optional, each state can choose whether to provide them in its Medicaid State Plan. *See* 42 U.S.C. § 1396a(a)(10)(A) (requiring state plans to provide at least the services listed in 42 U.S.C. §§ 1396d(a)(1)-(a)(5), (a)(17), (a)(21), (a)(28)); § 409.905, Fla. Stat. (listing mandatory Medicaid services); § 409.906, Fla. Stat. (listing the optional Medicaid services Florida provides).

3. Federal EPSDT Requirements

Under federal Medicaid law, states must provide EPSDT services for qualified children under age 21 when requested under the Medicaid state plan. 42 U.S.C. § 1396a(a)(43); 42 U.S.C. § 1396d(a)(4).

EPSDT services include periodic and age-appropriate health screenings (i.e. comprehensive health and developmental history, physical examinations, appropriate immunizations, laboratory tests, and health education), vision, dental, and hearing screenings, and appropriate follow-up treatment whenever a screening shows a follow-up treatment to be medically necessary. 42 U.S.C. §§ 1396d(r)(1)-(4). They also include:

> Such other necessary health care, diagnostic services, treatment, and other measures described in subsection (a) of this section to correct or ameliorate defects and physical and mental illness and conditions discovered by the screening services, whether or not such services are covered under the state plan.

42 U.S.C. § 1396d(r)(5).

Sections 5010 through 5360 of the State Medicaid Manual, which was promulgated by CMS and is binding on all state Medicaid programs, describes how states must provide EPSDT services to meet federal requirements. CMS State Medicaid Manual ch.1, § B.1, ch. 5 §§ 5010-5360 (available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.html).

B. Federal Law Allows States to Place Limitations on Medicaid Services, Including EPSDT Services.

The federal regulations and the CMS State Medicaid Manual expressly authorize states to place amount, duration, and scope limitations, as well as medical necessity limitations, on Medicaid services, including EPSDT services. 42 C.F.R. §§ 440.230(a), (b), (d). The CMS State Medicaid Manual expands on the federal regulation with respect to EPSDT services. It provides:

> Services under EPSDT must be sufficient in amount duration or scope to reasonably achieve their purpose. The amount, duration, or scope of EPSDT services to recipients may not be denied arbitrarily or reduced solely because of the diagnosis, type of illness, or condition. **Appropriate limits may be placed on EPSDT services based on medical necessity.**

* * *

> **[The states] make the determination as to whether the [EPSDT] service is necessary. You are not required to provide any items or services which you determine are not safe or effective or which are considered experimental.**
>
> * * *
>
> 42 C.F.R. 440.230 allows you to establish the amount duration and scope of services provided under the EPSDT benefit. Any limitations imposed must be reasonable and services must be sufficient to achieve their purpose (within the context of service the needs of individuals under age 21). You may define the service as long as the definition comports with the requirements of the statute in that all services included in § 1905(a) of the [Medicaid] Act that are **medically necessary to ameliorate or correct defects and physical or mental illnesses and conditions** discovered by the screening services are provided.

CMS State Medicaid Manual at §§ 5110, 5122.F., 5123 (emphasis added).

Thus, according to the federal regulations and CMS State Medicaid Manual, each state may limit Medicaid services, including EPSDT services, based on its own definition of "medical necessity," so long as the limitation is reasonable and services are provided in sufficient amounts to achieve their purpose.

C. Florida's Definition of Medical Necessity.

Florida has expressly incorporated "medical necessity" as a requirement for all Medicaid services. In sections 409.905 and 409.906, Florida Statutes, governing mandatory and optional Medicaid services in Florida, the legislature expressly instructs that all mandatory and optional Medicaid services "shall be provided only when medically necessary and in accordance with state and federal law." The legislature, further, gives AHCA the authority to determine whether medical necessity exists in any given case, including cases involving EPSDT services for children under 21 years of age. *See* § 409.905(2), Fla. Stat. ("The agency shall pay for early and periodic screening and diagnosis for a recipient under age 21 to ascertain physical and mental problems and conditions and all services determined by the agency to be medically necessary for the treatment, correction, or amelioration of these problems and conditions . . . .").

To guide its case-by-case determinations of medical necessity, AHCA has promulgated Florida Administrative Code Rule 59G-1.010(166). This Rule defines "medical necessity" to **exclude** experimental treatments, unproven treatments, ineffective treatments, cosmetic treatments, treatments that are inconsistent with generally accepted medical standards, and treatments or services that are excessive and purely for the convenience of the recipient or the recipient's family. *Id.* Specifically, the Rule states:

> (166) "Medically necessary" or "medical necessity" means that the medical or allied care, goods, or services furnished or ordered must:
>
> (a) Meet the following conditions:
>
> 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
>
> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
>
> 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
>
> 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available . . . statewide; and
>
> 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.
>
> * * *
>
> (c) The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.

Fla. Admin. Code R. 59G-1.010(166)(a), (c).

It should be noted, however, that subparagraph (a)(5) of the medical necessity definition does not apply when determining the medically necessity of private duty nursing services. Fla. Admin. Code R. 59G-4.261(4); *Florida Medicaid Private Duty Nursing Services Coverage Policy*, November 2016, incorporated by reference into Fla. Admin Code R. 59G-4.261, Section 1.3.6.

D. Analysis of the "Medical Necessity" Inquiry for EPSDT Services.

In *Moore v. Medows*, 324 Fed. Appx. 773 (11th Cir. 2009) (unpublished opinion), the Eleventh Circuit held that a private physician's opinion as to the "medical necessity" of a treatment for a child Medicaid recipient is not dispositive, and that the state Medicaid program also has a role in determining what medical measures are necessary to "correct or ameliorate" the child's medical condition. 324 Fed. Appx. at 774. Specifically, the *Medows* Court stated:

> While it is true that, after the 1989 amendments to the Medicaid Act, the state must fund any medically necessary treatment that [a child Medicaid recipient] requires, *Pittman v. Department of Health and Rehabilitative Services*, 998 F.2d 887, 891-92 (11th Cir. 1993), it does not follow that the state is wholly excluded from the process of determining what treatment is medically necessary. Instead, both the state and [treating] physician have roles in determining what medical measures are necessary to "correct or ameliorate" [a child Medicaid recipient's] medical conditions. *Rush v. Parham*, 625 F.2d 1150, 1155 (5th Cir. 1980); 42 C.F.R. 440.230 ("(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures."); *see* 42 U.S.C. § 1396d(r)(5). A private physician's word on medical necessity is not dispositive.

Id.

Thereafter, in *Moore v. Reese*, 637 F.3d 1220 (2011), the Eleventh Circuit approved and expanded on the *Medows* Court's reasoning, conducting a thorough review of the federal Medicaid statutes, regulations, manuals, and precedents, and summarizing them into six (6) "guiding principles."

> (1) [A State] is required to provide . . . services to [a child Medicaid recipient], who meets the EPSDT eligibility requirements **when such services are medically necessary to correct or ameliorate [his or her] illness and condition. . . .**

(2) A state Medicaid plan must include reasonable standards . . . for determining such eligibility for and the extent of medical assistance . . . and such standards must be "consistent with the objectives of the Medicaid Act, specifically, its EPSDT program. . . .

(3) **A state may adopt a definition of medical necessity that places limits on a physician's discretion. . . . A state may also limit required Medicaid services based upon its judgment of degree of medical necessity so long as such limitations do not discriminate on the basis of the kind of medical condition.** . . . Furthermore, a state may establish standards for individual physicians to use in determining what services are appropriate in a particular case and a treating physician is required to operate within such reasonable limitations as the state may impose.

(4) The treating physician assumes the primary responsibility of determining what treatment should be made available to his patients. **Both the treating physician and the state have roles to play, however, and [a] private physician's word on medical necessity is not dispositive.**

(5) **A state may establish the amount, duration, and scope of [medical services] provided under the required EPSDT benefit. The state is not required to provide medically unnecessary, albeit desirable, EPSDT service.** However, a state's provision of a required EPSDT benefit . . . must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

(6) **A state may place appropriate limits on a service based on such criteria as medical necessity. In so doing, a state can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis, and may present its own evidence of medical necessity in disputes between the state and Medicaid patients.**

Reese, 637 F.3d at 1255 (emphasis added, internal quotation marks and citations omitted).

There are two Florida district court opinions that applied the Florida Medicaid program's definition of medical necessity in Rule 59G-1.010(166) consistent with the federal law. *See Cabello v. Ag. for Health Care Admin.*, 79 So. 3d 123, 124 (Fla. 3d DCA 2012) (upholding the reduction of a child's Medicaid-paid services because the Hearing Officer's ruling was based on substantial and competent evidence in the record showing that the services provided were not

authorized as medically necessary, such as to meet the requirements of Medicaid's Home Health Services Program) (citing Fla. Admin. Code R. 59G-1.010(166)(a)); *Lorenzo v. Ag. for Health Care Admin.*, 985 So. 2d 703 (Fla. 4th DCA 2008) (upholding the denial of Medicaid-paid hyperbaric oxygen treatments for a child on grounds that there was no evidence that the treatment was an effective, non-experimental, medically necessary treatment for the patient's condition). There is, however, a previous decision from the Third District Court that is in conflict with federal law—*C.F. v. Department of Children and Families*, 934 So. 2d 1 (Fla. 3d DCA 2005).

In *C.F.*, the Third District erroneously held that more weight should be afforded a treating physicians' opinion regarding the "medical necessity" of a service and that the "medical necessity" definition is not the same for adults and children. The *C.F.* court, interpreting 42 U.S.C. § 1396a(42) and 42 U.S.C. § 1396d(a)(13), specifically found that "the hearing officer improperly applied the restrictive definition of 'medical necessity'" found in Rule 59G-1.010(166). According to the court, the hearing officer should have applied the federal, EPSDT definition of medical necessity for children. 934 So. 2d at 5-7. Although *C.F.* talks about a federal definition of medical necessity, there is no federal EPSDT definition of medical necessity; rather the only definition of medical necessity is found in Florida's Rule 59G-1.010(166). In fact, the federal government has not, through legislation or regulation, defined the term "medical necessity" for adults or children. Instead, the federal government has left the defining of this term to the states. 42 C.F.R. §§ 440.230(a), (b), (d).

Compounding the problem, the Third District also erroneously held that "[a] state agency must give considerable and substantial weight to the opinions of treating physicians" and "failure to credit the opinion of the treating physician must be accompanied by a showing of good cause." 934 So. 2d at 7 (citing *Snyder v. Dep't of Child. & Fams.*, 705 So. 2d 1067, 1068-69 (Fla. 1st DCA

1998)). Applying this standard to the case before it, the court found that "[h]ere, the Hearing Officer's reason for rejecting the pediatrician's opinion does not meet the burden of 'good cause.' The opinion of C.F.'s treating physician should have been given greater weight than the opinion of the [state] reviewer, who had never met C.F. or consulted with C.F.'s treating physician." *Id.*

The *C.F.* court's reliance on *Snyder*'s heightened deference to the treating physician's opinion is misplaced. *Snyder* erroneously relies on social security disability law to impose a treating physician rule in the context of Medicaid services.[2] The federal regulations governing the Social Security Act disability program at the time *Snyder* was decided expressly required deference be given to the treating physician and, thus, the requirement of special deference to the treating physician was legislatively imposed. 20 C.F.R. § 404.1527(c)(2); 20 C.F.R. § 416.927(c)(2).[3] By contrast, there are no legislatively imposed requirements regarding deference to the treating physician's opinion in the federal Medicaid law.[4] *See* 42 U.S.C. § 1396, et seq.; 42 C.F.R. § 430, et seq. And, as discussed throughout this memorandum, federal case law affords no deference to the treating physician's opinion in Medicaid cases and federal regulations no longer give any

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[2] Although not pertinent to this analysis, the *C.F.* court incorrectly applied the federal EPSDT requirements to services requested under the Florida Medicaid Home and Community-Based Waiver program, rather than under the Medicaid State Plan. 934 So. 2d at 2, 4, 6-7; *see also* 42 U.S.C. § 1396d(r).

[3] As of March 27, 2017, the federal regulations that govern the Social Security Act disability program no longer give deference to the treating physician. See 20 C.F.R. § 404.1520c(a) (Stating that "We will not defer or give any specific evidentiary weight, including controlling weight, to any medical opinion(s) or prior administrative medical finding(s), including those from your medical sources.")

[4] Importantly, in *Black & Decker Disability Plan v. Nord*, 538 U.S. 822 (2003), the United States Supreme Court held that courts may not require administrators of a federal statutory scheme to accord special weight to a treating physician nor may courts impose a special burden on administrators to explain when they credit reliable evidence that conflicts with a treating physician's evaluation absent a statute or regulation requiring such deference to a treating physician. *Id.* at 829-34.

deference at all to the treating physician in the context of the Social Security Act disability program. *Reese*, 637 F.3d at 1255; 20 C.F.R. § 404.1520c(a). Thus, the *C.F.* court's deference to the treating physician's opinion, where no statutory scheme imposes such deference, was in error.

In summary, states may place limits on Medicaid state plan services, including EPSDT services. Those limits include limitations based on amount, duration, and scope of services, and limitations on services based on the state's definition of "medical necessity." Additionally, a treating physician's opinion regarding the medical necessity of a service is not dispositive or accorded deference. Instead, the state can review the medical necessity of a treatment prescribed by a treating physician on a case-by-case basis and present its own evidence of whether the service is medically necessary. *Reese*, 637 F.3d at 1255-1261; *Medows*, 324 Fed. Appx. at 774.

AHCA is bound to follow the Eleventh Circuit's decisions interpreting federal law. The Eleventh Circuit cases of *Medows* and *Reese* were decided after, and presumably in consideration of, all intermediate Florida appellate court decisions which reached a result contrary to that decision (*see, e.g., Cook ex rel. Cook v. Agency for Persons with Disabilities*, 967 So. 2d 1002 (Fla. 1st DCA 2007), *C.F. v. Department of Children and Families*, 934 So. 2d 1 (Fla. 3d DCA 2005), and *Snyder v. Department of Children and Families*, 705 So. 2d 1067 (Fla. 1st DCA 1998)). AHCA, then, must follow *Medows* and *Reese* even if they conflict with earlier opinions of Florida District Courts of Appeal. Moreover, because it is proper for Florida courts to "accord[] unusual weight to a decision on an issue rendered by a federal circuit in which the state is located [when] deciding federal questions where there is no Supreme Court authority," Florida's District Courts of Appeal should properly defer to the Eleventh Circuit's opinions, especially the published opinion in *Reese*, when reviewing agency action taken in accordance with that decision. *See Pignato v. Great W. Bank*, 664 So. 2d 1011, 1015 (Fla. 4th DCA 1995).

RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

Guide to Explaining the Summary Memorandum

Effective Date: April 25, 2017

The concepts discussed in the April 25, 2017 Summary Memorandum can be summarized and explained as follows:

- The Medicaid program is a program in which the state and federal governments work together to pay for necessary medical services for the needy, in accordance with federal law and the state's Medicaid State Plan.

- According to federal law, each state's Medicaid program must provide early and periodic screening, diagnosis, and treatment (EPSDT) for children under the age of 21, when requested under its Medicaid State Plan (as opposed to a Medicaid waiver). EPSDT includes:

    - Health screenings (including comprehensive health and developmental history, physical exams, appropriate immunizations, lab test, and health education);
    - Vision, dental, and hearing screenings, and appropriate follow-up treatment when necessary; and
    - Other health care, diagnostic services, treatment, and other measures necessary to correct or ameliorate defects, physical illness, mental illness, and conditions discovered through screening services.

- Federal Medicaid law allows states to limit Medicaid-paid goods or services, including EPSDT for children under age 21. Important things to take away from the federal law are:

    - A state may limit goods and services, including EPSDT, based on amount, duration or scope, and/or based on medical necessity.
    - It is up to the state to decide whether a particular service is medically necessary. States are not required to provide any item or service that the state determines is not safe, not effective, or is considered experimental. States are not required to provide EPSDT that is desirable but not medically necessary.
    - If a state choses to place any limitations on EPSDT, including any limitation based on medical necessity, that limitation must be reasonable, and individual services must be provided in a sufficient amount, duration, and scope to achieve the purpose of the service.

- The Florida Medicaid program limits goods and services based on medical necessity. AHCA uses the definition of medical necessity at Florida Administrative Code Rule 59G-1.010(166), in all of its case-by-case Medicaid services determinations, including in cases where EPSDT is requested for a child under age 21. The only exception is that subsection

(5) of the definition, regarding convenience, does not apply in determining the level of private duty nursing (PDN) that is medically necessary for a child under age 21.

- Recent cases from the federal Eleventh Circuit Court of Appeals, *Moore v. Medows* and *Moore v. Reese*, clarify federal Medicaid law and guide the case-by-case determination of medical necessity in Florida. The following principles from these cases apply whether the medical necessity determination is made by AHCA, or by a DCF hearing officer through the fair hearing process:

    - There is no federal definition of medical necessity. Instead, the federal government has empowered each state to create its own definition of medical necessity and to limit Medicaid services, including EPSDT, based on that definition.
    - Both the state and the treating physician have roles in determining whether a good or services is medically necessary. The treating physician's opinion is not dispositive (i.e., is not the final word).
    - A state can review the medical necessity of a good or service prescribed by a treating physician on a case-by-case basis, and may present its own evidence of medical necessity in disputes between the State and Medicaid patients.

- There are two Florida district court opinions that applied the Florida Medicaid program's definition of medical necessity in Rule 59G-1.010(166), consistent with Federal law:

    - *Cabello v. Agency for Health Care Administration*, 79 So. 3d 123, 124 (Fla. 3d DCA 2012), upheld the reduction of a child's Medicaid-paid services because the Hearing Officer's ruling was based on competent and substantial evidence in the record showing that the services provided were not authorized as medically necessary, such as to meet the requirements of Medicaid's Home Health Services Program, and cited Fla. Administrative Code Rule 59G-1.010(166)(a); and
    - *Lorenzo v. Agency for Health Care Administration*, 985 So. 2d 703 (Fla. 4th DCA 2008), upheld the denial of Medicaid-paid hyperbaric oxygen treatments for a child on grounds that there was no evidence that the treatment was an effective, non-experimental, medically necessary treatment for the patient's condition.

- There is, however, a previous decision from the Third District that is in conflict with federal law—*C.F. v. Department of Children and Families*, 934 So. 2d 1 (Fla. 3d DCA 2005). *C.F.* is in conflict with federal law because it wrongly found that more weight should be afforded a treating physician's opinion regarding the medical necessity of services, that the medical necessity definition is not the same for adults and children, and that there is a federal definition of medical necessity when there is not. A more detailed explanation and a legal analysis of the reasons *C.F.* conflicts with federal law is located at pages 8 through 10 of the April 25, 2017 Summary Memorandum.