Synagis® (Palivizumab)

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Instructions for Use

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Community Plan Policy
• Synagis® (Palivizumab)

Coverage Rationale

See Benefit Considerations

Synagis (palivizumab) is proven and medically necessary to prevent serious respiratory syncytial virus disease (RSV) in high risk infants and young children when all of the following are met: [7-10,13]

- Administered during RSV season as defined by Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) or state or local health departments to confirm the start of the respiratory syncytial virus (RSV) "season"; and
- Monthly doses of Synagis does not exceed 15 mg/kg per dose; and
- Monthly dose of Synagis does not exceed 5 doses per single RSV "season"
  Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV "season," fewer than 5 monthly doses may be needed.
  and
- One of the following clinical situations:
  - Prematurity
    - Infants born before 29 weeks, 0 day's gestations who are < 12 months of age at the start of RSV "season."
  - Chronic Lung Disease (CLD)
    - Age 0 to < 12 months: Prophylaxis may be considered during the RSV "season" during the first year of life for preterm infants who develop chronic lung disease (CLD) of prematurity defined as gestational age < 32 weeks, 0 days and a requirement for > 21% oxygen for at least the first 28 days after birth.
    - Age ≥ 12 to < 24 months: Synagis is proven for use in pre-term infants born at < 32 weeks, 0 day's gestation who are ≥ 12 to < 24 months of age who required at least 28 days of oxygen after birth and who continue to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV "season."

- Congenital Heart Disease (CHD)
  - Age 0 to < 12 months: Infants and children with hemodynamically significant CHD who are born within 12 months of onset of RSV "season" and who will most likely benefit from immunoprophylaxis include:
    - Infants and children with acyanotic heart disease that are receiving medication to control congestive heart failure and will require cardiac surgical procedures.
    - Infants and children with moderate to severe pulmonary hypertension
    - Documentation that decisions regarding Synagis prophylaxis for infants with cyanotic heart defects in the first year of life were made in consultation with a pediatric cardiologist.
  - Age < 24 months: A postoperative dose for children who still require prophylaxis and who have undergone surgical procedures should be administered Synagis prophylaxis after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation.
    - Children who undergo cardiac transplantation during the RSV "season" may be considered for Synagis prophylaxis.
- Congenital abnormalities of the airway or neuromuscular disease
  - Age 0 to < 12 months: Infants and children with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough may be considered for prophylaxis during the first year of life.
- Immunocompromised children < 24 months of age
  - Synagis may be administered when used for prophylaxis in children who are receiving cancer chemotherapy or are severely immunocompromised although the efficacy of prophylaxis in this population is unknown (e.g., children who are receiving chemotherapy or undergo hematopoietic stem cell transplantation or solid organ transplantation).
- Cystic fibrosis (CF) with other qualifying indications
  - Age 0 to < 12 months: Infants and children with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis.
    a. Failure to thrive defined as weight for length less than the 10th percentile on a pediatric growth chart.
  - Age ≥ 12 to < 24 months: Continued use of Synagis prophylaxis in the second year may be considered for infants and children with manifestations of severe lung disease including:
    - Previous hospitalization for pulmonary exacerbation in the first year of life.
    - Abnormalities on chest radiography or chest computed tomography that persists when stable.
    - Weight for length less than the 10th percentile on a pediatric growth chart.

Synagis is unproven for the following situations:[9-10,13]

- Infants with chronic lung disease (CLD) who do not continue to require medical support in the second year of life.
- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus).
- Infants with cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure.
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy.
- Children in the second year of life unless otherwise indicated as proven above.
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (<29 weeks, 0 day's gestation) is present].
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present).
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab.
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children.
- Synagis prophylaxis for prevention of nosocomial disease.
- When Synagis prophylaxis is administered in any of the following scenarios:
  - Outside of the RSV "season"
  - In doses greater than needed to provide protection in the RSV "season"
  - In excess of 5 doses per single RSV "season"
  - To persons other than those at defined high risk, as specified above

- Treatment of symptomatic RSV disease.

Additional Information

In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV "season" in the state of Florida that could affect the timing of Synagis administration.[9]

- Despite varied onsets, the RSV "season" is of the same duration (5 months) in the different regions of Florida.
- On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants.
- Limited information is available concerning the burden of RSV disease among Native American populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.

For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% and RSV "season" offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is ≥ 10%. Use of specimens to determine the start of the RSV "season" requires that the number of specimens tested be statistically significant.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each

Diagnosis Code	Description
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D84.81	Immunodeficiency due to conditions classified elsewhere
D84.821	Immunodeficiency due to drugs
D84.822	Immunodeficiency due to external causes
D84.89	Other immunodeficiencies

Diagnosis Code	Description
D84.9	Immunodeficiency, unspecified
P07.21	Extreme immaturity of newborn, gestational age less than 23 completed weeks
P07.22	Extreme immaturity of newborn, gestational age 23 completed weeks
P07.23	Extreme immaturity of newborn, gestational age 24 completed weeks
P07.24	Extreme immaturity of newborn, gestational age 25 completed weeks
P07.25	Extreme immaturity of newborn, gestational age 26 completed weeks
P07.26	Extreme immaturity of newborn, gestational age 27 completed weeks
P07.31	Preterm newborn, gestational age 28 completed weeks
P26.0	Tracheobronchial hemorrhage originating in the perinatal period
P26.1	Massive pulmonary hemorrhage originating in the perinatal period
P26.8	Other pulmonary hemorrhages originating in the perinatal period
P26.9	Unspecified pulmonary hemorrhage originating in the perinatal period
P27.0	Wilson-Mikity syndrome
P27.1	Bronchopulmonary dysplasia originating in the perinatal period
P27.8	Other chronic respiratory diseases originating in the perinatal period
P27.9	Unspecified chronic respiratory disease originating in the perinatal period
P29.30	Pulmonary hypertension of newborn
P29.38	Other persistent fetal circulation
Q20.0	Common arterial trunk
Q20.1	Double outlet right ventricle
Q20.2	Double outlet left ventricle
Q20.3	Discordant ventriculoarterial connection
Q20.4	Double inlet ventricle
Q20.5	Discordant atrioventricular connection
Q20.6	Isomerism of atrial appendages
Q20.8	Other congenital malformations of cardiac chambers and connections
Q20.9	Congenital malformation of cardiac chambers and connections, unspecified
Q21.0	Ventricular septal defect
Q21.1	Atrial septal defect
Q21.2	Atrioventricular septal defect
Q21.3	Tetralogy of Fallot
Q21.4	Aortopulmonary septal defect
Q21.8	Other congenital malformations of cardiac septa
Q21.9	Congenital malformation of cardiac septum, unspecified
Q22.0	Pulmonary valve atresia
Q22.1	Congenital pulmonary valve stenosis
Q22.2	Congenital pulmonary valve insufficiency
Q22.3	Other congenital malformations of pulmonary valve
Q22.4	Congenital tricuspid stenosis
Q22.5	Ebstein's anomaly
Q22.6	Hypoplastic right heart syndrome
Q22.8	Other congenital malformations of tricuspid valve

Diagnosis Code	Description
Q22.9	Congenital malformation of tricuspid valve, unspecified
Q23.0	Congenital stenosis of aortic valve
Q23.1	Congenital insufficiency of aortic valve
Q23.2	Congenital mitral stenosis
Q23.3	Congenital mitral insufficiency
Q23.4	Hypoplastic left heart syndrome
Q23.8	Other congenital malformations of aortic and mitral valves
Q24.1	Levocardia
Q24.2	Cor triatriatum
Q24.3	Pulmonary infundibular stenosis
Q24.4	Congenital subaortic stenosis
Q24.5	Malformation of coronary vessels
Q24.6	Congenital heart block
Q24.8	Other specified congenital malformations of heart
Q25.0	Patent ductus arteriosus
Q25.1	Coarctation of aorta
Q25.21	Interruption of aortic arch
Q25.29	Other atresia of aorta
Q25.3	Supravalvular aortic stenosis
Q25.40	Congenital malformation of aorta unspecified
Q25.41	Absence and aplasia of aorta
Q25.42	Hypoplasia of aorta
Q25.43	Congenital aneurysm of aorta
Q25.44	Congenital dilation of aorta
Q25.45	Double aortic arch
Q25.46	Tortuous aortic arch
Q25.47	Right aortic arch
Q25.48	Anomalous origin of subclavian artery
Q25.49	Other congenital malformations of aorta
Q25.5	Atresia of pulmonary artery
Q25.6	Stenosis of pulmonary artery
Q25.71	Coarctation of pulmonary artery
Q25.72	Congenital pulmonary arteriovenous malformation
Q25.79	Other congenital malformations of pulmonary artery
Q25.8	Other congenital malformations of other great arteries
Q25.9	Congenital malformation of great arteries, unspecified
Q26.0	Congenital stenosis of vena cava
Q26.1	Persistent left superior vena cava
Q26.2	Total anomalous pulmonary venous connection
Q26.3	Partial anomalous pulmonary venous connection
Q26.4	Anomalous pulmonary venous connection, unspecified
Q26.8	Other congenital malformations of great veins

Diagnosis Code	Description
Q26.9	Congenital malformation of great vein, unspecified
Q31.1	Congenital subglottic stenosis
Q31.2	Laryngeal hypoplasia
Q31.3	Laryngocele
Q31.5	Congenital laryngomalacia
Q31.9	Congenital malformation of larynx, unspecified
Q32.0	Congenital tracheomalacia
Q32.1	Other congenital malformations of trachea
Q32.3	Congenital stenosis of bronchus
Q32.4	Other congenital malformations of bronchus
Q33.0	Congenital cystic lung
Q33.2	Sequestration of lung
Q33.3	Agenesis of lung
Q33.4	Congenital bronchiectasis
Q33.6	Congenital hypoplasia and dysplasia of lung
Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)
Z51.11	Encounter for antineoplastic chemotherapy
Z92.21	Personal history of antineoplastic chemotherapy

Background

Palivizumab is a humanized murine monoclonal immunoglobulin produced by recombinant DNA technology which has neutralizing and fusion-inhibitory activity against RSV.[7]

Lower respiratory tract infections (LRTI) have been documented as the leading cause of infectious disease hospitalizations among infants according to a recent analysis of hospital admissions in the United States (US). Respiratory syncytial virus (RSV) is one of the most common causes of LRTI.[2]

According to the Morbidity and Mortality Weekly Report (MMWR), Respiratory Syncytial Virus — United States, July 2012–June 2014, it has been estimated that 57,527 hospitalizations and 2.1 million outpatient visits among children aged <5 years in the United States has been associated with RSV.[3] To describe RSV seasonality (defined as onset, offset, peak, and duration) nationally, by U.S. Department of Health and Human Services (HHS) regions and for the state of Florida, the Centers for Disease Control and Prevention (CDC) analyzes RSV laboratory detections reported to the National Respiratory and Enteric Virus Surveillance System (NREVSS). This NREVSS surveillance data may be used to identify RSV activity and coordinate timing of immunoprophylaxis with palivizumab. The American Academy of Pediatrics has recommended that high-risk infants and young children are likely to benefit from immunoprophylaxis based on gestational age, certain underlying medical conditions, and RSV seasonality.[14]

Benefit Considerations

Benefits for the use of palivizumab to prevent complications of RSV infection in defined high-risk patients are for a maximum of five doses one month apart. Coverage begins at the start of the RSV season, which varies in different parts of the United States. Physicians should consult CDC surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/) or their state or local health departments to confirm the start of the RSV season before administering palivizumab.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit

coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. See the Policy and Procedure addressing the treatment of serious rare diseases.

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member's specific plan document to determine benefit coverage.

Clinical Evidence

Proven

NREVSS is a laboratory-based system that monitors geographical and temporal trends for various respiratory and enteric viruses, including RSV activity, to the CDC.

Nationally, across three RSV seasons, lasting from the week ending July 5, 2014 through July 1, 2017, the median RSV onset occurred at week 41 (mid-October), and lasted 31 weeks until week 18 (early May). The median national peak occurred at week 5 (early February).[14]

Researchers in The Cochrane Collaboration conducted a literature review to assess the effectiveness and safety of palivizumab prophylaxis compared with placebo, or another type of prophylaxis, in reducing the risk of complications (hospitalization due to RSV infection) in high-risk infants and children.[12] Additionally they assessed the cost-utility of palivizumab prophylaxis compared with no prophylaxis in infants and children in different risk groups. A literature search was conducted and randomized, controlled trial (RCTs) comparing palivizumab prophylaxis with a placebo, no prophylaxis or another type of prophylaxis in preventing serious lower respiratory tract disease caused by RSV in pediatric patients at high risk were included in the evaluation along with cost-effectiveness analyses and cost-utility analyses comparing palivizumab prophylaxis with no prophylaxis. Of the 7 available RCTs, 3 compared palivizumab with a placebo in a total of 2831 patients, and 4 compared palivizumab with motavizumab in a total of 8265 patients. All RCTs were sponsored by the drug manufacturing company. A statistically significant reduction in RSV hospitalizations (RR 0.49, 95% CI 0.37 to 0.64) was found with palivizumab prophylaxis compared to placebo. When compared to motavizumab, palivizumab recipients showed a non-significant increase in the risk of RSV hospitalizations (RR 1.36, 95% CI 0.97 to 1.90). Adverse events (AE) related to the study drug was similar in both cases. In regard to economic evidence (EE), researchers included 34 studies that reported cost-effectiveness and/or cost-utility data for palivizumab prophylaxis compared with no prophylaxis, in high-risk children with different underlying medical conditions. The overall quality of EEs found was good, but the variations in modeling approaches were considerable across the studies, leading to big differences in cost-effectiveness results. Cost-effectiveness of palivizumab prophylaxis depended on the consumption of resources taken into account by the study authors; and on the cost-effectiveness threshold set by the healthcare sector in each country. Researchers concluded that there is evidence that palivizumab prophylaxis is effective in reducing the frequency of hospitalizations due to RSV infection in children who are at higher risk (such as children with chronic lung disease, congenital heart disease or those born preterm) of acquiring severe RSV infections, when compared to placebo. Additionally, results from economic evaluations of palivizumab prophylaxis are inconsistent, implying that economic findings must be interpreted with caution. The incremental cost-effectiveness ratio (ICER) values varied considerably across studies, from highly cost-effective to not cost-effective.

Unproven

MAKI was a multicenter, double-blind, placebo-controlled trial to explore the causal role of RSV infection in the pathogenesis of wheezing during the first year of life using palivizumab. Healthy preterm infants (n=429) born at a gestational age of 33 to 35 weeks were randomized in a 1:1 ratio to receive either monthly palivizumab (dose = 15 mg/kg) injections (n=214) or placebo (n=215) during the RSV season.[11] The primary outcome evaluated was number of parent reported wheezing days in the first year of life. Secondary outcomes assessed included were the number of days with bronchodilator use, the number of RSV infections confirmed by means of a nasopharyngeal swab positive for RSV RNA with or without medical attention, the number of hospitalizations for laboratory-proven RSV infection, the number of wheezing episodes, and the prevalence of recurrent

wheeze. Researchers reported that treatment with palivizumab (median number of injections was 4) resulted in a relative reduction of 61% (95% confidence interval, 56 to 65) in the total number of wheezing days during the first year of life (930 of 53,075 days in the RSV-prevention group [1.8%] vs. 2309 of 51,726 days [4.5%] in the placebo group). Additionally, the proportion of infants with recurrent wheezing was lower in the RSV-prevention group than in the placebo group (11.2% vs. 20.9%, p=0.005). More co-infections during non-wheezing episodes were reported in the RSV-prevention group than in the placebo group (114 of 291 swabs [39%] vs. 70 of 233 swabs [30%], p=0.03). Researchers concluded that in otherwise healthy preterm infants, prophylactic treatment with palivizumab reduced the total number of wheezing days in the first year of life among preterm infants with a gestational age of 33 to 35 weeks. These findings implicate RSV infection as an important mechanism of recurrent wheeze during the first year of life in this population.

A 2014 Cochrane Review assessed the efficacy and safety of palivizumab compared with placebo, no prophylaxis or other prophylaxis, in preventing hospitalization and mortality from respiratory syncytial virus (RSV) infection in children with cystic fibrosis (CF).[6] A database review identified one randomized controlled trial comparing five monthly doses of palivizumab to placebo in CF infants up to two years old. At 6 months follow-up, there were no clinically meaningful differences in outcomes reported and at 12 months follow-up, there were no significant differences reported between groups in number of Pseudomonas bacterial colonization or change in weight-to-height ratio. Authors concluded that while the overall incidence of adverse events was similar in both groups, it is not possible to draw firm conclusions on the safety and tolerability of respiratory syncytial virus prophylaxis with palivizumab in CF infants. Additional randomized studies are warranted to establish the safety and efficacy of palivizumab in children with cystic fibrosis.

The significance of these conclusions must be validated in additional randomized, controlled trials in order to be considered for inclusion into the recommendations of the Committee on Infectious Diseases (COID) of the American Academy of Pediatrics (AAP) on palivizumab prophylaxis of infants and young children.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Synagis (palivizumab) is FDA-approved for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. Safety and efficacy were established in infants with chronic lung disease of prematurity, formerly termed bronchopulmonary dysplasia (BPD), infants with a history of premature birth (≤ 35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD).[7]

Safety and efficacy of Synagis has not been established for treatment of RSV disease.[7]

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for SYNAGIS® (palivizumab). Local Coverage Determinations (LCDs) do not exist.

In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals. (Accessed June 10, 2020)

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Policy History/Revision Information

Date	Summary of Changes

10/01/2020	**Applicable Codes**
	• Updated list of applicable ICD-10 diagnosis codes to reflect annual edits:
	  ○ Added D84.81, D84.821, D84.822, and D84.89
	  ○ Removed D84.8
	Supporting Information
	• Archived previous policy version 2020D0005U

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.