Synagis® (palivizumab)
(Intramuscular)

Document Number: IC-0120

Last Review Date: 07/28/2015
Date of Origin: 11/28/2011
Dates Reviewed: 12/13/11, 02/07/2013, 02/25/2014, 08/26/2014, 07/28/2015

I. Length of Authorization

- Authorize for a maximum of 5 doses during RSV season (five monthly doses of 15 mg/kg IM).
- In infants and children < 24 months, already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO).

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 15mg/kg IM monthly up to 5 doses
- Synagis 50 mg vial: 1 vial every 28 days
- Synagis 100 mg vial: 2 vials every 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 5 billable units every 28 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Prevention of serious lower respiratory tract disease caused by Respiratory syncytial virus (RSV)

Infant/Child Age at Start of RSV Season±	Criteria (must meet at least one of the following)
<12 months (1st year of life)	▪ GA <29 wks, 0 d (otherwise healthy) ▪ CLD of prematurity (GA <32 wks, 0 d and >21% O2 x first 28 d after birth) ▪ Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly – impairs ability to clear secretions ▪ Profoundly immunocompromised ▪ CF with CLD and/or nutritional compromise

Infant/Child Age at Start of RSV Season±	Criteria (must meet at least one of the following)
≤ 12 months (1st year of life)	▪ CHD (hemodynamically significant) with acyanotic HD on CHF medications and will require cardiac surgery or moderate to severe PH. For cyanotic heart defects consult a pediatric cardiologist
>12 months (2nd year of life)	▪ CLD of prematurity (GA <32 wks, 0 d and >21% O2 x first 28 d after birth) and medical support (chronic systemic steroids, diuretic therapy, or supplemental O2) within 6 months before start of 2nd RSV season ▪ CF with severe lung disease* or weight for length <10th percentile
<24 months (2nd year of life)	▪ Cardiac transplant during RSV season ▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO ▪ Profoundly immunocompromised

GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease; O2=oxygen; HD=heart disease; CHF=chronic heart failure; PH=pulmonary hypertension; CF=cystic fibrosis; ECMO=extracorporeal membrane oxygenation
*Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the 1st year of life, abnormalities on chest radiography [chest X-ray], or chest computed tomography [chest CT] that persist when stable

±RSV Season

- There is variability in the onset and offset of RSV season. Generally it runs from November to April within the continental US. A maximum of 5 doses during RSV season provides 6 months of RSV prophylaxis.
- Alaska- Due to the varied epidemiology of RSV infection, clinicians can use RSV surveillance data by the state of Alaska to determine the onset and offset of RSV season.
- Florida- Data from the Florida Department of Health can be used to determine the onset and offset of RSV season in different regions of Florida.
- Native American Indian infants- There is limited information about the burden of RSV infection among American Indian populations. Prophylaxis can be considered for Navajo and White Mountain Apache infants in the 1st year of life.
- Despite onset and offset of RSV infection in some states or regions, only a maximum of 5 doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. For example if prophylaxis is initiated in January, the 4th and final dose, will be administered in April. For eligible infants born during RSV season, fewer than 5 monthly doses will be needed.

Synagis (palivizumab) will NOT be approved in the following scenarios

Infant/Child Age at Start of RSV Season	Deny
>12 months (2nd year of life)	▪ Based on prematurity alone ▪ CLD without medical support (chronic systemic steroids, diuretic therapy, or supplemental O_2) ▪ CHD ▪ Otherwise healthy children in 2nd year of life
Any age	▪ Breakthrough RSV hospitalization** ▪ Hemodynamically *insignificant* CHD*** ▪ CHD lesions corrected by surgery (unless on CHF meds) ▪ CHD and mild cardiomyopathy not on medical therapy ▪ CHD in 2nd year of life
No specific age defined	▪ GA ≥29 wks, 0 d (otherwise healthy) ▪ Asthma prevention ▪ Reduce wheezing episodes ▪ Down Syndrome ▪ CF (otherwise healthy) ▪ Healthcare-associated RSV disease****

**If any infant or child is receiving palivizumab prophylaxis and experiences a breakthrough RSV hospitalization, discontinue palivizumab, because the likelihood of a second RSV hospitalization in the same season is extremely low.

***Examples of hemodynamically insignificant CHD: secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus.

**** No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease; palivizumab use is not recommended for this purpose.

IV. Renewal Criteria

Renewal authorization is not applicable.

V. Dosage/Administration

Indication	Dose
RSV Prophylaxis	The recommended dose is 15 mg/kg intramuscularly once a month throughout the RSV season.

VI. Billing Code/Availability Information

Jcode:

90378 – Synagis (MedImmune) 50, 100 mg injection: 1 billable unit = 50 mg

NDC:

N/A

VII. References

1. Synagis [package insert]. Gaithersburg, MD; MedImmune, LLC; March 2014. Accessed June 2015.
2. American Academy of Pediatrics. Position Statement. Updated guidance for palivizumab prophylaxis among Infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics 2014; 134;415. DOI: 10.1542/peds.2014-1665.

Appendix 1 – Covered Diagnosis Codes

ICD-9 Codes	Diagnosis
079.6	Respiratory syncytial virus (RSV)
279.00	Hypogammaglobulinemia, unspecified
279.01	Selective IgA immunodeficiency
279.02	Selective IgM immunodeficiency
279.03	Other selective immunoglobulin deficiencies
279.04	Congenital hypogammaglobulinemia
279.05	Immunodeficiency with increased IgM
279.06	Common variable immunodeficiency
279.09	Other deficiency of humoral immunity
279.10	Immunodeficiency with predominant T-cell defect, unspecified
279.11	Digeorge's syndrome
279.12	Wiskott-aldrich syndrome
279.13	Nezelof's syndrome
279.19	Other deficiency of cell-mediated immunity
279.2	Combined immunity deficiency
279.3	Unspecified immunity deficiency
279.41	Autoimmune lymphoproliferative syndrome
279.49	Autoimmune disease, not elsewhere classified
279.50	Graft-versus-host disease, unspecified
279.51	Acute graft-versus-host disease
279.52	Chronic graft-versus-host disease
279.53	Acute on chronic graft-versus-host disease
279.8	Other specified disorders involving the immune mechanism
279.9	Unspecified disorder of immune mechanism
358.00	Myasthenia gravis without (acute) exacerbation
358.01	Myasthenia gravis with (acute) exacerbation

ICD-9 Codes	Diagnosis
358.1	Myasthenic syndromes in diseases classified elsewhere
358.2	Toxic myoneural disorders
358.30	Lambert-Eaton syndrome, unspecified
358.31	Lambert-Eaton syndrome in neoplastic disease
358.39	Lambert-Eaton syndrome in other diseases classified elsewhere
358.8	Other specified myoneural disorders
358.9	Myoneural disorders, unspecified
416.0	Primary pulmonary hypertension
416.1	Kyphoscoliotic heart disease
416.2	Chronic pulmonary embolism
416.8	Other chronic pulmonary heart diseases
416.9	Chronic pulmonary heart disease, unspecified
428.0	Congestive heart failure, unspecified
491.0	Simple chronic bronchitis
491.1	Mucopurulent chronic bronchitis
491.20	Obstructive chronic bronchitis without exacerbation
491.21	Obstructive chronic bronchitis with (acute) exacerbation
491.22	Obstructive chronic bronchitis with acute bronchitis
491.8	Other chronic bronchitis
491.9	Unspecified chronic bronchitis
493.20	Chronic obstructive asthma, unspecified
493.21	Chronic obstructive asthma with status asthmaticus
493.22	Chronic obstructive asthma with (acute) exacerbation
496	Chronic airway obstruction, not elsewhere classified
745.0	Common truncus
745.10	Complete transposition of great vessels
745.11	Double outlet right ventricle
745.12	Corrected transposition of great vessels
745.19	Other transposition of great vessels
745.2	Tetralogy of fallot
745.3	Common ventricle
745.4	Ventricular septal defect
745.5	Ostium secundum type atrial septal defect
745.60	Endocardial cushion defect, unspecified type

ICD-9 Codes	Diagnosis
745.61	Ostium primum defect
745.69	Other endocardial cushion defects
745.7	Cor biloculare
745.8	Other bulbus cordis anomalies and anomalies of cardiac septal closure
745.9	Unspecified defect of septal closure
746.00	Congenital pulmonary valve anomaly, unspecified
746.01	Atresia of pulmonary valve, congenital
746.02	Stenosis of pulmonary valve, congenital
746.09	Other congenital anomalies of pulmonary valve
746.1	Tricuspid atresia and stenosis, congenital
746.2	Ebstein's anomaly
746.3	Congenital stenosis of aortic valve
746.4	Congenital insufficiency of aortic valve
746.5	Congenital mitral stenosis
746.6	Congenital mitral insufficiency
746.7	Hypoplastic left heart syndrome
746.81	Subaortic stenosis
746.82	Cor triatriatum
746.83	Infundibular pulmonic stenosis
746.84	Obstructive anomalies of heart, not elsewhere classified
746.85	Coronary artery anomaly
746.86	Congenital heart block
746.87	Malposition of heart and cardiac apex
746.89	Other specified congenital anomalies of heart
746.9	Unspecified congenital anomaly of heart
747.0	Patent ductus arteriosus
747.10	Coarctation of aorta (preductal) (postductal)
747.11	Interruption of aortic arch
747.20	Anomaly of aorta, unspecified
747.21	Anomalies of aortic arch
747.22	Atresia and stenosis of aorta
747.29	Other anomalies of aorta
747.31	Pulmonary artery coarctation and atresia
747.32	Pulmonary arteriovenous malformation

ICD-9 Codes	Diagnosis
747.39	Other anomalies of pulmonary artery and pulmonary circulation
747.40	Anomaly of great veins, unspecified
747.41	Total anomalous pulmonary venous connection
747.42	Partial anomalous pulmonary venous connection
747.49	Other anomalies of great veins
747.5	Absence or hypoplasia of umbilical artery
747.83	Persistent fetal circulation
748.5	Agenesis, hypoplasia, and dysplasia of lung
748.60	Anomaly of lung, unspecified
748.61	Congenital bronchiectasis
748.69	Other congenital anomalies of lung
765.21	Less than 24 completed weeks of gestation
765.22	24 completed weeks of gestation
765.23	25-26 completed weeks of gestation
765.24	27-28 completed weeks of gestation
765.25	29-30 completed weeks of gestation
765.26	31-32 completed weeks of gestation
765.27	33-34 completed weeks of gestation
770.3	Pulmonary hemorrhage
770.7	Chronic respiratory disease arising in the perinatal period
V04.82	Need for prophylactic vaccination and inoculation against respiratory syncytial virus (RSV)

ICD-10	ICD-10 Description
B97.4	Respiratory syncytial virus as the cause of diseases classified elsewhere
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy

ICD-10	ICD-10 Description
D80.8	Other immunodeficiencies with predominantly antibody defects
D80.9	Immunodeficiency with predominantly antibody defects, unspecified
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
D81.4	Nezelof's syndrome
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
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D82.9	Immunodeficiency associated with major defect, unspecified
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D84.0	Lymphocyte function antigen-1 [LFA-1] defect
D84.1	Defects in the complement system
D84.8	Other specified immunodeficiencies
D84.9	Immunodeficiency, unspecified
D89.3	Immune reconstitution syndrome
D89.810	Acute graft-versus-host disease
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
D89.89	Other specified disorders involving the immune mechanism, not elsewhere classified

ICD-10	ICD-10 Description
D89.9	Disorder involving the immune mechanism, unspecified
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
G70.1	Toxic myoneural disorders
G70.2	Congenital and developmental myasthenia
G70.80	Lambert-Eaton syndrome, unspecified
G70.81	Lambert-Eaton syndrome in disease classified elsewhere
G70.89	Other specified myoneural disorders
G70.9	Myoneural disorder, unspecified
G73.1	Lambert-Eaton syndrome in neoplastic disease
G73.3	Myasthenic syndromes in other diseases classified elsewhere
I27.0	Primary pulmonary hypertension
I27.1	Kyphoscoliotic heart disease
I27.2	Other secondary pulmonary hypertension
I27.81	Cor pulmonale (chronic)
I27.82	Chronic pulmonary embolism
I27.89	Other specified pulmonary heart diseases
I27.9	Pulmonary heart disease, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.9	Heart failure, unspecified
J20.5	Acute bronchitis due to respiratory syncytial virus
J41.0	Simple chronic bronchitis

ICD-10	ICD-10 Description
J41.1	Mucopurulent chronic bronchitis
J41.8	Mixed simple and mucopurulent chronic bronchitis
J42	Unspecified chronic bronchitis
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified
J44.9	Chronic obstructive pulmonary disease, unspecified
M35.9	Systemic involvement of connective tissue, 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
P07.32	Preterm newborn, gestational age 29 completed weeks
P07.33	Preterm newborn, gestational age 30 completed weeks
P07.34	Preterm newborn, gestational age 31 completed weeks
P07.35	Preterm newborn, gestational age 32 completed weeks
P07.36	Preterm newborn, gestational age 33 completed weeks
P07.37	Preterm newborn, gestational age 34 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
P29.3	Persistent fetal circulation
Q20.0	Common arterial trunk
Q20.1	Double outlet right ventricle
Q20.2	Double outlet left ventricle

ICD-10	ICD-10 Description
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
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
Q23.9	Congenital malformation of aortic and mitral valves, unspecified
Q24.0	Dextrocardia
Q24.1	Levocardia
Q24.2	Cor triatriatum
Q24.3	Pulmonary infundibular stenosis
Q24.4	Congenital subaortic stenosis

ICD-10	ICD-10 Description
Q24.5	Malformation of coronary vessels
Q24.6	Congenital heart block
Q24.8	Other specified congenital malformations of heart
Q24.8	Other specified congenital malformations of heart
Q24.9	Congenital malformation of heart, unspecified
Q25.0	Patent ductus arteriosus
Q25.1	Coarctation of aorta
Q25.2	Atresia of aorta
Q25.3	Supravalvular aortic stenosis
Q25.4	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
Q26.9	Congenital malformation of great vein, unspecified
Q27.0	Congenital absence and hypoplasia of umbilical artery
Q33.1	Accessory lobe of lung
Q33.2	Sequestration of lung
Q33.3	Agenesis of lung
Q33.4	Congenital bronchiectasis
Q33.5	Ectopic tissue in lung
Q33.6	Congenital hypoplasia and dysplasia of lung
Q33.8	Other congenital malformations of lung
Q33.9	Congenital malformation of lung, unspecified
Z23	Encounter for immunization

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A