Navigating Severe RSV* Disease and SYNAGIS
A guide for specialty pharmacy providers

* RSV = respiratory syncytial virus.

INDICATION
SYNAGIS is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:

- with a history of premature birth (≤35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

IMPORTANT SAFETY INFORMATION
SYNAGIS is contraindicated in children who have had a previous significant hypersensitivity reaction to SYNAGIS.

Please see page 38 for additional Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Table of contents

Section 1: Severe RSV disease and SYNAGIS
— What is severe RSV disease?
— What is SYNAGIS and how can it help children at high risk for severe RSV disease?

Section 2: Patient access
— Reimbursement and coverage basics
— Benefit design and reimbursement

Section 3: Patient assistance resources
— Prescription assistance for your customers
— Independent Non-profit Organizations

Section 4: Supporting HCPs and caregivers
— Communicating with HCPs and caregivers
— Cradle with Care℠

Section 5: Ensuring accuracy
— Data reporting
— Guide to coding for SYNAGIS

Section 6: Frequently asked questions
— Severe RSV disease
— SYNAGIS
— Cradle with Care

Section 7: Summary
— Important Safety Information

Section 8: Glossary

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
SPPs have their own section on healthcare providers page of Synagis.com

Now you can access information for SPPs by clicking the “For Specialty Pharmacists” link on Synagis.com for healthcare professionals page.

There is a variety of information available on the site covering topics such as:

- Severe respiratory syncytial virus (RSV) disease and RSV seasonality
- How SYNAGIS may be able to help children at high risk for severe RSV disease
- Effectively communicating with healthcare providers (HCPs) and caregivers
- Reimbursement and coverage information for SYNAGIS
- Frequently asked questions

Visit synagis.com/hcp/specialty-pharmacy-provider-resources to download and order helpful tools and resources about severe RSV disease and SYNAGIS.

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Section 1: Severe RSV disease and SYNAGIS
— What is severe RSV disease?
— What is SYNAGIS and how can it help children at high risk for severe RSV disease?

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Section 1: Severe RSV Disease and SYNAGIS

What is severe RSV disease?

Most children with RSV disease suffer mild to moderate cold-like symptoms. For some high-risk babies, RSV disease can be more serious. Premature infants born at ≤35 weeks gestation and children ≤24 months old who have certain heart or lung conditions are at high risk for developing a serious lung infection, such as bronchiolitis and/or pneumonia.1,2

- Severe RSV disease is the leading cause of hospitalization among infants <1 year of age in the US3
- High-risk babies may be at risk of RSV-related hospitalization, resulting in higher hospital resource utilization4,5

Severe RSV disease can have serious consequences for high-risk children6

Across the US, RSV season varies over time and from location to location5

- The start and end of RSV season can vary year to year, state to state, and can even vary within communities in the same region7,8
- Throughout much of the US, RSV season begins in the fall and runs into spring—although year-round RSV activity has been reported in Florida and Puerto Rico7-11
- Children at high risk for severe RSV disease should receive adequate protection with SYNAGIS. The average length of RSV season is about 5 months8
- You may obtain RSV surveillance reports directly from the RSVAalert® website at www.rsvalert.com or via your AstraZeneca representative. You may also call 1-877-633-4411

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Important Safety Information

Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to SYNAGIS. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to SYNAGIS. The relationship between these reactions and the development of antibodies to SYNAGIS is unknown. If a significant hypersensitivity reaction occurs with SYNAGIS, its use should be permanently discontinued. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of SYNAGIS.

Please see page 38 for additional Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Section 2: Patient access

— Reimbursement and coverage basics
— Benefit design and reimbursement
## Types of insurance coverage

A patient’s out-of-pocket (OOP) expense for SYNAGIS will vary depending on their insurance coverage, as shown in the tables below. It is important that you work with the patient’s insurance provider to choose the fulfillment pathway with the lowest OOP cost for the patient.

### Coverage Scenario

<table>
<thead>
<tr>
<th>Coverage Scenario</th>
<th>Explanation</th>
</tr>
</thead>
</table>
| Employer-sponsored Health Plan                         | • Patient pays portion of monthly premium through employer (deducted from their pay)  
• Employer also contributes to premium                  |
| Health Insurance Marketplaces (Exchanges)              | • Patient buys policy through federal, state, or partnership marketplace (depending on the state) and pays monthly premium  
• Patient will likely be responsible for paying a copay or coinsurance depending on their insurance coverage |
| Medicaid (Fee-for-service [FFS] or Managed Medicaid)    | • Patient pays lower premiums than commercial members, or may pay a zero premium  
• Patient may have higher OOP costs for SYNAGIS          |
| Uninsured/Not Covered                                  | • All expenses are self-pay  
• If a patient is without prescription coverage or can’t afford their medication, AstraZeneca may be able to help |

### Common* Coverage for SYNAGIS

- **Commercial Plans:** Aetna, United Healthcare, Cigna, Coventry
- **Pharmacy Benefit Management (PBM) Systems:** Express Scripts (ESI), Medco, Caremark PBM, SXC Health Solutions
- **Managed Medicaid Plans:** Molina Healthcare, Centene, Wellcare
- **FFS/Traditional Medicaid Plans:** Medicaid-TX, Medicaid-AL, Medicaid-NC

*Other plans or systems may exist in your area

---

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Benefit design and reimbursement

Health plans reimburse drugs through either their pharmacy or medical benefit. The pharmacy benefit of a plan covers the costs of medications dispensed through pharmacies. The medical benefit covers the cost of medical care, including physician visits, lab/diagnostic testing, hospital visits, and clinics.

Historically, specialty drugs have been covered under a plan’s medical benefit because these drugs are often obtained and administered by a physician (e.g., by injection/infusion). However, payers are increasingly shifting coverage of specialty products to the pharmacy benefit for better control of utilization and costs.

Copayment vs. coinsurance

A copayment (or copay) is a fixed-dollar amount that is paid each visit for certain services. Usually a patient is responsible for a copayment each time they visit a doctor and for each prescription medication filled. For example, with a health insurance plan, a patient may pay a $15 copayment for each primary care physician visit, $25 copayment for a specialist visit, and $20 for each brand-name prescription.

Coinsurance is a percent of what the cost of care is. A patient is also responsible for paying the coinsurance amount. For example, if a medication is $1,000 per month and they have 30% coinsurance, they will pay the pharmacy $300 and their health plan will pay the balance.

Issues with customer reimbursement

SPPs face unique challenges managing seasonal therapies such as SYNAGIS. Reimbursement challenges may differ for each SPP. The chart below reflects some of the most common challenges.

<table>
<thead>
<tr>
<th>Reimbursement Challenges</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary Insurance</td>
<td>Primary insurance plan that covers most of a patient’s expenses and a secondary plan that picks up the rest. This may be a challenge if secondary coverage does not utilize the same SPPs</td>
</tr>
<tr>
<td>Secondary Medicaid (FFS or Managed Medicaid)</td>
<td>Medicaid sometimes works as a secondary insurance for uninsured or underinsured, paying for coinsurances and copayments. Problems arise when the contracted SPP for the patient’s primary plan is not contracted with their state Medicaid plan and therefore cannot bill for the balance even though the patient has coverage</td>
</tr>
<tr>
<td>Pharmacy Carve-outs</td>
<td>Many employers have elected to “Carve-out” pharmacy benefits to a PBM company. When this happens, all benefits are managed under the PBM, and as a result the patient’s benefits for SYNAGIS may be unknown</td>
</tr>
<tr>
<td>Out-of-State Plan</td>
<td>When the plan that issues coverage or provides prior authorization (PA) for a member is out-of-state (e.g., Blue Card plans), the SPP may be required to bill the local “host” plan where the patient is being serviced</td>
</tr>
</tbody>
</table>

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Section 3: Patient assistance resources

— Prescription assistance for your customers
— Independent Non-profit Organizations
Section 3: Patient assistance resources
Prescription assistance for your customers

There are several programs to help ensure that a financial burden won’t keep high-risk children from getting SYNAGIS. If you have a customer who needs assistance paying for SYNAGIS, they may qualify for support such as the Copay Savings Program for SYNAGIS or support from an Independent Non-Profit Organization (INO). Be sure that the patient’s HCP is aware of available assistance programs, as well as their eligibility requirements. The details of each program are outlined in this section.

The copay Savings Program for SYNAGIS

The Copay Savings Program for SYNAGIS assists qualified commercially insured patients with their copays for SYNAGIS:

- Eligible patients may have access to a virtual debit account funded with up to $2,000 to assist with OOP costs for SYNAGIS
- Patients are responsible for the first $30 of each dose of SYNAGIS

Who is eligible for the Copay Savings Program for SYNAGIS? (Must meet all criteria)

The Copay Savings Program for SYNAGIS assists qualified commercially insured patients with their copays for SYNAGIS:

- Patients with a copay/co-insurance >$30
- Patients not covered by Medicaid, TRICARE, or other state or federal government healthcare programs
- Patients with a prescription for SYNAGIS that is consistent with the product label

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Enrolling in the Copay Savings Program for SYNAGIS

How the program works

Prescriber gives the parent/caregiver the SYNAGIS affordability brochure, which includes information about the Copay Savings Program for SYNAGIS

If the patient meets all of the program eligibility requirements, the pharmacy, home care, or prescriber’s office can process the patient’s enrollment in the program by visiting www.synagiscopaysavings.com or by calling Access 360™ at 1-844-ASK-A360

The pharmacy, home care, or prescriber’s office that processes the patient’s copay collects the first $30 of the patient’s SYNAGIS copay (per dose), and utilizes the SYNAGIS Copay Program account number to cover the balance, up to $2,000 per season

Once copay is paid, medication is shipped to site of care

Enrollment may be done quickly and easily at www.synagiscopaysavings.com. Please call the Help Desk at 1-877-858-5452 if you need access to the portal.
If you need additional information on the Copay Savings Program for SYNAGIS, call 1-844-ASK-A360 or visit www.myaccess360.com.

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
### Comprehensive referral and reimbursement support with Access 360

<table>
<thead>
<tr>
<th>Coverage and reimbursement support</th>
<th>Referral submission</th>
<th>Patient access programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access 360 has a team of dedicated specialists available to assist in identification of coverage specific to MedImmune products</td>
<td>Access 360 provides a weekly reconciliation report to all contracted SPPs, which includes all patient referrals submitted and date of submission. If you need assistance or have questions, please call 1-844-ASK-A360</td>
<td>MedImmune is dedicated to helping patients have unencumbered access to necessary MedImmune products. Our patient access programs assist patients with high OOP costs</td>
</tr>
<tr>
<td>Access 360 can offer support with the referral process as well as address barriers to access, such as prior authorization, denials, and patient OOP costs</td>
<td></td>
<td>MedImmune provides complimentary products to eligible patients who are uninsured or rendered uninsured</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If a patient is without prescription coverage or can’t afford their medication, AstraZeneca may be able to help</td>
</tr>
</tbody>
</table>

### Billing and Coding Support

- ICD-9-CM and ICD-10-CM diagnosis codes
- National Drug Codes
- Healthcare Common Procedure Coding System for healthcare supplies not identified by CPT codes

Please refer to the SYNAGIS Coding Resource, which can be found in Section 5 of this guide, for potential codes to consider. For additional coding or coverage support please call 1-844-ASK-A360

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Independent Non-profit Organizations (INO)

About INOs*
If a patient doesn’t qualify for the Copay Savings Program for SYNAGIS or needs additional financial assistance, he or she may be able to obtain support through an INO. INOs facilitate access to medical care for patients with chronic or life-threatening illness. These organizations help patients overcome financial and other barriers to medical care. Some INOs have limitations on the types of medication covered.

Who may be eligible?
Each INO has specific criteria for determining a patient’s eligibility to receive assistance. Criteria may include:

- Medical qualifications
- Insurance coverage
- Income requirements

For more information, or to be connected to an INO that may be able to help your patients, please call Access 360™ at 1-844-ASK-A360

*INOs are not affiliated with MedImmune. MedImmune makes no representations as to insurance coverage or financial support available through these programs. MedImmune provides a grant to the INOs and has no involvement or vested interest in how funds are disbursed.

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
**INO support process**

<table>
<thead>
<tr>
<th>How the process works</th>
</tr>
</thead>
<tbody>
<tr>
<td>MedImmune provides a grant to the INO and has no involvement in how funds are disbursed</td>
</tr>
<tr>
<td>Prescriber refers patient to an INO</td>
</tr>
<tr>
<td>Parent/caregiver contacts INO and applies for copay support on behalf of the patient</td>
</tr>
<tr>
<td>If eligible, patients will receive a grant from the INO to assist with OOP medication costs</td>
</tr>
<tr>
<td>The INO will notify the parent/caregiver, pharmacy, and prescriber of the decision, along with instructions for how the grant may be used</td>
</tr>
<tr>
<td>A grant from the INO acts as a secondary payer to assist with medication OOP costs. Once the copay is paid, medication is shipped to site of care</td>
</tr>
</tbody>
</table>

INOs have awarded hundreds of millions of dollars in copayment assistance to patients in need.
Section 4: Supporting HCPs and caregivers
   — Communicating with HCPs and caregivers
   — Cradle with Care℠

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Section 4: Supporting HCPs and caregivers

Communicating with HCPs and caregivers

When it comes to helping to protect high-risk children from severe RSV disease, everyone involved should be on the same page. Below are suggestions for effectively communicating with HCPs and caregivers.

Establishing HCP collaboration

- Try to identify a single point-of-contact in each HCP office as well as a secondary contact if the primary is ever out of the office.
- Consider keeping a file with all SYNAGIS patient information in one place.
- Have action items and requests from SYNAGIS coordinators circled or clearly outlined on the SYNAGIS patient form/list.
- Have up-to-date status and follow-up executed by end-of-day Friday so that planning for the following week can take place.
- Know the business days/hours of the HCP office and plan shipments according to their schedule, especially around holidays.
- Share with HCPs that patient eligibility for various benefit options should be considered carefully.
- Carefully coordinate critical monthly injections in November, December, and January.
- When appropriate, remind HCPs that some high-risk babies may need SYNAGIS for a second season.
- Consider sending a letter to HCPs to remind them that they may have patients who are eligible for a second season or send a general letter at the end of RSV season to alert HCPs about second season.

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Communicating with caregivers and parents

- Be sure that parents and caregivers of high-risk babies understand what SYNAGIS is and how it may help protect their children from severe RSV disease
  - Explain that SYNAGIS is not a vaccine, but rather an FDA-approved prescription injection of antibodies that is given monthly to help protect high-risk children from severe RSV disease throughout the RSV season
- Each dose of SYNAGIS provides protection for about 28–30 days
- If a high-risk baby is prescribed SYNAGIS, he or she will need to continue receiving monthly shots throughout RSV season
- A high-risk baby needs to keep getting SYNAGIS for as long as it is prescribed
- Be sure that parents and caregivers are aware of the Cradle with Care℠ program and how it can support them and children with severe RSV disease who were prescribed SYNAGIS
- Remind parents and caregivers to talk to their child’s doctor about what’s right for their child
- Be sure to outline next steps required to receive SYNAGIS in any communications with a parent or caregiver. Include relevant contact information for a parent or caregiver to follow-up and confirm next steps
- Inform parents about available assistance programs, including the Copay Savings Program for SYNAGIS. If a patient is without prescription coverage or can’t afford their medication, AstraZeneca may be able to help

Remember to assess the needs of each HCP practice and customer on an individual basis

IMPORTANT SAFETY INFORMATION

Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count <50,000/microliter) and injection site reactions have been reported.

Please see page 38 for additional Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Cradle with Care support programs

Cradle with Care can help support you as you work with caregivers and other members of the healthcare team to make sure high-risk children receive protection against severe RSV disease. This section explains how the program can help you and how to speak to caregivers about Cradle with Care.

Cradle with Care supports patients and members of the collaborative healthcare team by addressing 3 key areas:

**Reminders**
Important reminders and alerts about RSV season, baby’s dosing schedule, or appointments

**Education**
Parents can stay informed about RSV, SYNAGIS, and what makes their baby vulnerable to severe RSV disease

**Support**
Parents can gain access to financial assistance and other support resources

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
As you’re speaking to caregivers about SYNAGIS, make sure they’re aware of the Cradle with Care program. Below are some suggestions of how you can introduce the program to caregivers followed by descriptions of the resources that are available upon program enrollment.

**Sample introductions**

“Do you know about the Cradle with Care program? It is a free program for children who are receiving SYNAGIS.”

“Cradle with Care provides dosing for SYNAGIS and RSV season reminders, as well as information about RSV and support throughout the RSV season.”

“You can enroll online at www.cradlewithcare.com, or I can send you an informational brochure that includes a business reply card so you can sign up for the program through the mail. Do you have any questions about the program I can answer?”

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Cradle with Care resources

**Educational Video**
RSV, SYNAGIS, and your baby. This video is available upon request on the Cradle with Care website (www.cradlewithcare.com).
It reinforces the urgency to help protect high-risk children from severe RSV disease, and provides HCP and parent testimonials and an overview of who’s at high risk for severe RSV disease.

**Cradle with Care Consumer Welcome Kit**
Introduces the Cradle with Care program, tools, and resources to consumers. It also includes a business reply card for program enrollment, confirms enrollment and includes SYNAGIS and severe RSV disease overviews, as well as highlights of what consumers can expect, such as educational materials.

**Reminder Program for SYNAGIS**
Text message, email, and direct mail reminders to help caregivers remember important appointments for injections of SYNAGIS.

**Cradle with Care Consumer Website**
Provides a brief overview of who is at high risk for severe RSV disease, as well as a testimonial video and information about program assistance.

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Section 5: Ensuring accuracy

— Data reporting
— Guide to Coding for SYNAGIS

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Section 5: Ensuring accuracy

Data reporting

Understanding data field requirements
This section identifies the reports, status, and other terminologies that are necessary to implement data reporting as part of the Assignment of Benefits (AOB) Agreement/Contract between SPPs and MedImmune.

Required reports
The Referred Prescription/Physician Order Detail Report is sent weekly to MedImmune at data@medimmune.com no later than 5:30 PM ET on the first business day of each week. It contains cumulative performance data from July 1 of the applicable RSV season through the close of business the previous Friday. This report contains details of referred prescription and/or physician order activity. Some of the most important fields for entry include the following:

<table>
<thead>
<tr>
<th>Field</th>
<th>Format</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Referral Received</td>
<td>mm/dd/yyyy</td>
<td>Date referral was received for current season</td>
</tr>
<tr>
<td>Access 360™ ID</td>
<td>7 digit alphanumeric</td>
<td>Referral number assigned to referrals received from Access 360 (if not received from Access 360, 7 zeros is acceptable)</td>
</tr>
<tr>
<td>Gestational Age</td>
<td>numeric (two digits)</td>
<td>Discrete number - in weeks (not a range)</td>
</tr>
<tr>
<td>Clinical Criteria</td>
<td>see values, enter a number 1-9</td>
<td>Field value determined by SPP based on AAP guidelines; see Clinical Criteria definitions for details, report only one value that is most appropriate. Values: 1, 2, 3, 4, 5, 6, 7, 8, 9</td>
</tr>
<tr>
<td>Doses Authorized</td>
<td>2 digit numeric (01, 02, 03, 04, 05, 06, etc.; use 99 if authorized doses unavailable)</td>
<td># allowed by insurer (for patients in Active status, this number should be 01, 02, 03, 04, 05, 06, etc. or 99 if authorized doses unavailable)</td>
</tr>
<tr>
<td>Status</td>
<td>Text</td>
<td>General referral status - updated each week Values: Active, Denied, Discharged, Triaged, Pending, Hold</td>
</tr>
<tr>
<td>Status Description</td>
<td>Text</td>
<td>Specific status explanation (see descriptions above)</td>
</tr>
<tr>
<td>Plan Name</td>
<td>Text</td>
<td>Name of patient’s insurance provider (Insurer; only PBM or adjudicator if Insurer not available, may also record Employer Group) Record full name of Payor including state. Example: FL Medicaid, BCBS of MA instead of Medicaid or BCBS</td>
</tr>
<tr>
<td>Primary Payer</td>
<td>Text</td>
<td>If Primary Payor is a PBM, enter PBM name here</td>
</tr>
<tr>
<td>Plan Type</td>
<td>Text</td>
<td>Indicate the type of plan – must be either “Commercial”, “FFS Medicaid” or “Managed Medicaid”</td>
</tr>
<tr>
<td>Benefit Type</td>
<td>Text</td>
<td>Indicate the type of benefit – must be either “RX” or “Medical”</td>
</tr>
<tr>
<td>Secondary Payer</td>
<td>Text or N/A</td>
<td>Indicate secondary Payor if applicable, or N/A if not available</td>
</tr>
</tbody>
</table>

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Field Definitions Clinical Criteria
Each eligible patient for SYNAGIS must be assigned a field value based upon clinical criteria, such as age at the start of RSV season, and other risk factors.

How to determine clinical criteria value
Refer to the clinical criteria field definitions categorized by number in your AOB contract
Select the appropriate number based upon the patient's age and any other risk factors
Fill in clinical criteria reports with the appropriate number for each patient

Filling out reports properly will help to ensure that high-risk children receive the medication they need without delay

Each patient will fall into one of 6 major categories:
Active, Denied, Discharged, Hold, Pending, or Triaged

<table>
<thead>
<tr>
<th>Status definition</th>
<th>Acceptable descriptions (required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>HCP is currently receiving shipments for patient dosing</td>
<td>HCP is currently receiving shipments for patient dosing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Status definition</th>
<th>Acceptable descriptions (required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denied</td>
<td></td>
</tr>
<tr>
<td>Distributor was not able to service patient (i.e., patient never received shipment) because the patient did not meet Payer’s criteria/not medically necessary or policy (no coverage for SYNAGIS, etc.)</td>
<td>Did not meet insurers criteria/not medically necessary</td>
</tr>
<tr>
<td></td>
<td>No coverage for SYNAGIS</td>
</tr>
</tbody>
</table>

IMPORTANT SAFETY INFORMATION
As with any intramuscular injection, SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder
Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays

Please see page 38 for additional Important Safety Information and accompanying full Prescribing Information, including Patient Information.
## Discharged

<table>
<thead>
<tr>
<th>Status definition</th>
<th>Acceptable descriptions (required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient is no longer actively being worked with by the SPP. Patient had received at least one shipment but has discontinued, completed shipments, or a patient previously categorized as “Hold” for which SPP has determined will be unable to be activated for shipment</td>
<td>Therapy complete, Formerly in HOLD – Family financial decision</td>
</tr>
<tr>
<td></td>
<td>Insurance change, Formerly in HOLD – Family convenience decision</td>
</tr>
<tr>
<td></td>
<td>Patient deceased, Formerly in HOLD – MD decision</td>
</tr>
<tr>
<td></td>
<td>Patient moved, Formerly in HOLD – No response from office</td>
</tr>
<tr>
<td></td>
<td>Non-compliance to therapy, Formerly in HOLD – No response from family</td>
</tr>
<tr>
<td></td>
<td>Reached authorized dose limit</td>
</tr>
</tbody>
</table>

## Hold

<table>
<thead>
<tr>
<th>Status definition</th>
<th>Acceptable descriptions (required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPP is actively working with the patient to facilitate access to SYNAGIS, but has not yet been able to activate the shipment</td>
<td>Payer approved, pending season start, Family financial decision</td>
</tr>
<tr>
<td></td>
<td>Payer not reviewing until mm/dd/yyyy, Family convenience decision</td>
</tr>
<tr>
<td></td>
<td>Patient hospitalized, MD decision</td>
</tr>
<tr>
<td></td>
<td>Home care coordination, No response from office</td>
</tr>
<tr>
<td></td>
<td>Secondary insurance coordination, No response from family</td>
</tr>
<tr>
<td></td>
<td>No insurance</td>
</tr>
</tbody>
</table>
### Data reporting (cont’d)

<table>
<thead>
<tr>
<th>Pending</th>
<th>Status definition</th>
<th>Acceptable descriptions (required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPP has received referred prescription and/or physician order and is working to determine patient’s benefits and make decision on activation. Any referred prescription and/or physician order that is undergoing a PA process must be listed as Pending</td>
<td>New referred prescription and/or physician order</td>
<td>Pending PA</td>
</tr>
<tr>
<td></td>
<td>Incomplete referred prescription and/or physician order</td>
<td>Pending family response</td>
</tr>
<tr>
<td></td>
<td>Verifying benefits</td>
<td>Pending MD response</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Triaged</th>
<th>Status definition</th>
<th>Acceptable descriptions (required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distributor was not able to service patient due to insurance provider contractual requirement. Referred prescription and/or physician order should be triaged to another Network SPP if SPP is able to determine the appropriate one, or back to the provider with appropriate direction</td>
<td>Unable to determine/returned to MD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unable to determine/returned to Access 360™</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physician must purchase drug</td>
<td></td>
</tr>
<tr>
<td></td>
<td>To (enter specific name of SPP referred prescription and/or physician order was sent to)</td>
<td></td>
</tr>
</tbody>
</table>

**IMPORTANT SAFETY INFORMATION**

Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count <50,000/microliter) and injection site reactions have been reported.

Please see page 38 for additional Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Access 360 provides coding and coverage support at 1-877-778-9010. This guide contains potential codes to consider related to products supported by Access 360.

This guide is for informational purposes only and is not intended as coverage or coding advice. MedImmune cannot provide specific reimbursement rates, and does not guarantee reimbursement. You should verify the appropriate reimbursement information for services or items you provide. Contact the insurer to determine a patient’s current benefits and limitations.

**National Drug Code (NDC)**
The National Drug Code (NDC) is a universal, unique, 3-segment number identifying drugs by manufacturer, dosage, and package size. The Health Insurance Portability and Accountability Act (HIPAA) format for electronic claim submission requires an 11-digit format for NDC codes. Electronic claims may be denied for drugs billed without a valid 11-digit NDC.

Contact your patient’s health plan to determine claim submission requirements and to determine accurate reporting of NDC codes.

<table>
<thead>
<tr>
<th>11-digit NDC (for electronic claims)</th>
<th>10-digit NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage</td>
<td>Code</td>
</tr>
<tr>
<td>50 mg vial</td>
<td>60574-4114-01</td>
</tr>
<tr>
<td>100 mg vial</td>
<td>60574-4113-01</td>
</tr>
</tbody>
</table>

Submitting accurate codes and claims is important to ensure proper reimbursement of services. The chart below lists potential Common Procedural Terminology (CPT) codes for your reference when submitting claims for your patients of SYNAGIS.

**Supply and administration of RSV immunoprophylaxis**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>90378</td>
<td>Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each</td>
</tr>
<tr>
<td>96372</td>
<td>Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular</td>
</tr>
</tbody>
</table>

**Healthcare Common Procedure Coding System (HCPCS)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9562</td>
<td>Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
</tbody>
</table>

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Guide to Coding of SYNAGIS (cont’d)

SYNAGIS
When filing claims for SYNAGIS, providers often indicate a diagnosis code reflecting the patient’s condition. Some examples of diagnosis codes that may be appropriate for the care of RSV prophylaxis candidates are listed below. It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate. The use of the following codes does not guarantee reimbursement.

International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification = ICD-9-CM/ICD-10-CM

Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>Description</th>
<th>ICD-10-CM</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>765.00</td>
<td>Extreme immaturity, unspecified [weight]</td>
<td>P07.00*</td>
<td>Extremely low birth weight newborn, unspecified weight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P07.10*</td>
<td>Other low birth weight newborn, unspecified weight</td>
</tr>
<tr>
<td>765.10</td>
<td>Other preterm infants, unspecified [weight]</td>
<td>P07.00*</td>
<td>Extremely low birth weight newborn, unspecified weight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P07.10*</td>
<td>Other low birth weight newborn, unspecified weight</td>
</tr>
<tr>
<td>765.20</td>
<td>Unspecified weeks of gestation</td>
<td>P07.20</td>
<td>Extreme immaturity of newborn, unspecified weeks of gestation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P07.30</td>
<td>Preterm newborn, unspecified weeks of gestation</td>
</tr>
<tr>
<td>765.21</td>
<td>Less than 24 completed weeks of gestation</td>
<td>P07.21</td>
<td>Extreme immaturity of newborn, gestational age less than 23 completed weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P07.22</td>
<td>Extreme immaturity of newborn, gestational age 23 completed weeks</td>
</tr>
<tr>
<td>765.22</td>
<td>24 completed weeks of gestation</td>
<td>P07.23</td>
<td>Extreme immaturity of newborn, gestational age 24 completed weeks</td>
</tr>
<tr>
<td>765.23</td>
<td>25-26 completed weeks of gestation</td>
<td>P07.24</td>
<td>Extreme immaturity of newborn, gestational age 25 completed weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P07.25</td>
<td>Extreme immaturity of newborn, gestational age 26 completed weeks</td>
</tr>
<tr>
<td>765.24</td>
<td>27-28 completed weeks of gestation</td>
<td>P07.26</td>
<td>Extreme immaturity of newborn, gestational age 27 completed weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P07.31</td>
<td>Preterm newborn, gestational age 28 completed weeks</td>
</tr>
<tr>
<td>765.25</td>
<td>29-30 completed weeks of gestation</td>
<td>P07.32</td>
<td>Preterm newborn, gestational age 29 completed weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P07.33</td>
<td>Preterm newborn, gestational age 30 completed weeks</td>
</tr>
<tr>
<td>765.26</td>
<td>31-32 completed weeks of gestation</td>
<td>P07.34</td>
<td>Preterm newborn, gestational age 31 completed weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P07.35</td>
<td>Preterm newborn, gestational age 32 completed weeks</td>
</tr>
<tr>
<td>765.27</td>
<td>33-34 completed weeks of gestation</td>
<td>P07.36</td>
<td>Preterm newborn, gestational age 33 completed weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P07.37</td>
<td>Preterm newborn, gestational age 34 completed weeks</td>
</tr>
<tr>
<td>765.28</td>
<td>35 completed weeks of gestation</td>
<td>P07.38</td>
<td>Preterm newborn, gestational age 35 completed weeks</td>
</tr>
</tbody>
</table>


Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
## Guide to Coding of SYNAGIS (cont’d)

### Diagnosis Codes (cont’d)

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>Description</th>
<th>ICD-10-CM</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>770.7</td>
<td>Bronchopulmonary Dysplasia/Chronic Lung Disease of Prematurity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chronic respiratory disease arising in the perinatal period</td>
<td>P27.1</td>
<td>Bronchopulmonary dysplasia originating in the perinatal period</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P27.8</td>
<td>Other chronic respiratory diseases originating in the perinatal period</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P27.9</td>
<td>Unspecified chronic respiratory disease originating in the perinatal period</td>
</tr>
</tbody>
</table>

### Hemodynamically Significant Congenital Heart Disease

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>Description</th>
<th>ICD-10-CM</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>425.4</td>
<td>Other primary cardiomyopathies</td>
<td>I42.9</td>
<td>Cardiomyopathy, unspecified</td>
</tr>
<tr>
<td>428.0</td>
<td>Congestive heart failure, unspecified</td>
<td>I50.9</td>
<td>Heart failure, unspecified</td>
</tr>
<tr>
<td>745.0</td>
<td>Common truncus</td>
<td>Q20.0</td>
<td>Common arterial trunk</td>
</tr>
<tr>
<td>745.1</td>
<td>Transposition of great vessels</td>
<td>Q20.3</td>
<td>Discordant ventriculoarterial connection</td>
</tr>
<tr>
<td>745.11</td>
<td>Double outlet right ventricle</td>
<td>Q20.1</td>
<td>Double outlet right ventricle</td>
</tr>
<tr>
<td>745.2</td>
<td>Tetralogy of Fallot</td>
<td>Q21.3</td>
<td>Tetralogy of Fallot</td>
</tr>
<tr>
<td>745.4</td>
<td>Ventricular septal defect</td>
<td>Q21.0</td>
<td>Ventricular septal defect</td>
</tr>
<tr>
<td>745.5</td>
<td>Ostium secundum type atrial septal defect</td>
<td>Q21.1</td>
<td>Atrial septal defect</td>
</tr>
<tr>
<td>745.6</td>
<td>Endocardial cushion defect</td>
<td>Q21.2</td>
<td>Atrioventricular septal defect</td>
</tr>
<tr>
<td>745.9</td>
<td>Unspecified defect of septal closure</td>
<td>Q21.9</td>
<td>Congenital malformation of cardiac septum, unspecified</td>
</tr>
<tr>
<td>746.0</td>
<td>Congenital anomalies of pulmonary valve</td>
<td>Q22.3</td>
<td>Other congenital malformations of pulmonary valve</td>
</tr>
<tr>
<td>746.1</td>
<td>Tricuspid atresia and stenosis, congenital</td>
<td>Q22.4</td>
<td>Congenital tricuspid stenosis</td>
</tr>
<tr>
<td>746.2</td>
<td>Ebstein’s anomaly</td>
<td>Q22.5</td>
<td>Ebstein’s anomaly</td>
</tr>
</tbody>
</table>

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
### Diagnosis Codes (cont’d)

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>Description</th>
<th>ICD-10-CM</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>746.3</td>
<td>Congenital stenosis of aortic valve</td>
<td>Q23.0</td>
<td>Congenital stenosis of aortic valve</td>
</tr>
<tr>
<td>746.4</td>
<td>Congenital insufficiency of aortic valve</td>
<td>Q23.1</td>
<td>Congenital insufficiency of aortic valve</td>
</tr>
<tr>
<td>746.5</td>
<td>Congenital mitral stenosis</td>
<td>Q23.2</td>
<td>Congenital mitral stenosis</td>
</tr>
<tr>
<td>746.6</td>
<td>Congenital mitral insufficiency</td>
<td>Q23.3</td>
<td>Congenital mitral insufficiency</td>
</tr>
<tr>
<td>746.7</td>
<td>Hypoplastic left heart syndrome</td>
<td>Q23.4</td>
<td>Hypoplastic left heart syndrome</td>
</tr>
<tr>
<td>746.8</td>
<td>Other specified congenital anomalies of heart</td>
<td>Q24.8</td>
<td>Other specified congenital malformations of heart</td>
</tr>
<tr>
<td>746.85</td>
<td>Coronary artery anomaly</td>
<td>Q24.5</td>
<td>Malformation of coronary vessels</td>
</tr>
<tr>
<td>746.9</td>
<td>Unspecified congenital anomaly of heart</td>
<td>Q20.9</td>
<td>Congenital malformation of cardiac chambers and</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>connections, unspecified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Q24.9</td>
<td>Congenital malformation of heart, unspecified</td>
</tr>
<tr>
<td>747.0</td>
<td>Patent ductus arteriosus</td>
<td>Q25.0</td>
<td>Patent ductus arteriosus</td>
</tr>
<tr>
<td>747.1</td>
<td>Coarctation of aorta</td>
<td>Q25.1</td>
<td>Coarctation of aorta</td>
</tr>
<tr>
<td>747.11</td>
<td>Interruption of aortic arch</td>
<td>Q25.2</td>
<td>Atresia of aorta</td>
</tr>
<tr>
<td>747.2</td>
<td>Other congenital anomalies of aorta</td>
<td>Q25.4</td>
<td>Other congenital malformations of aorta</td>
</tr>
<tr>
<td>747.3</td>
<td>Anomalies of pulmonary artery</td>
<td>Q25.79</td>
<td>Other congenital malformations of pulmonary artery</td>
</tr>
<tr>
<td>747.4</td>
<td>Congenital anomalies of great veins</td>
<td>Q26.9</td>
<td>Congenital malformation of great vein, unspecified</td>
</tr>
<tr>
<td>747.41</td>
<td>Total anomalous pulmonary venous connection</td>
<td>Q26.2</td>
<td>Total anomalous pulmonary venous connection</td>
</tr>
<tr>
<td>747.42</td>
<td>Partial anomalous pulmonary venous connection</td>
<td>Q26.3</td>
<td>Partial anomalous pulmonary venous connection</td>
</tr>
</tbody>
</table>

This list represents many of the diagnoses of patients with hemodynamically significant CHD who were enrolled in the pivotal CHD clinical trial involving SYNAGIS. Other diagnoses and codes associated with hemodynamically significant CHD may also be considered.

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Section 6: Frequently asked questions

— Severe RSV disease
— SYNAGIS
— Cradle with Care℠
Section 6: Frequently asked questions
Severe RSV disease FAQs

The questions in this section may arise when speaking with caregivers about RSV, SYNAGIS, and Cradle with CareSM.

Q. What is RSV and when does RSV season begin and end?

A. Like the flu, RSV is a seasonal virus. The season start varies from one part of the country to the next, but it usually starts in the fall and continues into the spring. In some parts of the country, the length of the RSV season may be different. You may obtain RSV surveillance reports directly from the RSVAlert® website at www.rsvalert.com. You may also call 1-877-633-4411.

Q. How serious is RSV disease?

A. Most children with RSV disease suffer mild to moderate cold-like symptoms. For some high-risk babies, RSV disease can be more severe. Premature infants born at ≤35 weeks gestation and children ≤24 months of age with certain heart or lung conditions are at high risk for developing a serious lung infection, such as bronchiolitis and/or pneumonia.

Q. How easy is it to catch RSV?

A. Like the flu, RSV can be spread by sneezing and coughing or by physical contact, such as touching or shaking hands. RSV can live up to 5 hours on countertops and other surfaces and spreads very quickly in daycare centers and crowded households. RSV infects nearly all children by their second birthday.

Q. What are the signs and symptoms of a severe RSV infection?

A. Some signs and symptoms of severe RSV disease include:
   - Fast or troubled breathing
   - Bluish skin color due to a lack of oxygen (cyanosis) in more severe cases
   - Gasping for breath
   - Spread-out nostrils
   - Wheezing

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Q. What is SYNAGIS?

A. SYNAGIS is a prescription medication that is used to help prevent a serious lung disease caused by RSV in pediatric patients:
   - with a history of premature birth (≤35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
   - with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
   - with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

Q. Is SYNAGIS a vaccine?

A. No. Though not a vaccine, SYNAGIS is an FDA-approved prescription injection of antibodies that is given monthly to help protect high-risk children from severe RSV disease throughout the RSV season. Each dose provides protection for about 28–30 days.¹

Q. What are the side effects of SYNAGIS?

A. Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count <50,000/microliter) and injection site reactions have been reported.

Q. How do I report an adverse event?

A. To report a suspected adverse reaction or receive additional medical information, call MedImmune at 1-877-633-4411.

Q. How many SYNAGIS shots does a high-risk baby need?

A. The recommended dose of SYNAGIS is 15 mg/kg of body weight given monthly by intramuscular injection. The first dose of SYNAGIS should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season.

Q. If a high-risk baby looks healthy, are monthly SYNAGIS shots still necessary?

A. Yes. The efficacy of SYNAGIS at doses less than 15 mg/kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Q. Will high-risk babies need SYNAGIS for a second RSV season?

A. Most high-risk babies won’t need SYNAGIS for a second season. But some babies are still at high risk for severe RSV disease in their second year and may need SYNAGIS for more than one RSV season.

Q. What should I do if insurance won’t cover SYNAGIS?

A. While many health plans cover SYNAGIS, the levels of coverage and the requirements for getting it can vary. If a patient is without prescription coverage or can’t afford their medication, AstraZeneca may be able to help. Direct them to call 1-844-ASK-A360 to speak with a representative.

Cradle with Care℠ FAQs

Q. What is the benefit of the program?

A. Cradle with Care promotes compliance with recommended therapy through appointment reminders, provides access to education about RSV, and offers information about financial support.

Q. How do I sign up for the Cradle with Care program?

A. There are two ways to sign up.
   1. I can mail you the Cradle with Care brochure, which has a form and instructions on how to sign up by mail
   2. If you want to sign up using the website, visit www.cradlewithcare.com and follow the step-by-step instructions

Q. How do Spanish-speaking parents/caregivers enroll?

A. All enrollment materials are also available in Spanish. Parents/caregivers must sign the Spanish version of the opt-in page so they receive communications in Spanish.

Q. Do I have to enroll in Cradle with Care if my child is receiving SYNAGIS?

A. You do not have to enroll to receive SYNAGIS; however, you will need to enroll in Cradle with Care in order to receive doctor visit reminders and other helpful tools offered by the program. The doctor can still provide you with appointment reminders and other educational material without your having to sign up for the Cradle with Care program.

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Q. What do appointment reminders tell me to do?
A. The appointment reminders are designed to promote compliance with recommended therapy. Parents/caregivers are instructed to talk to their doctor to schedule appointments.

Q. Where can I receive information on financial assistance?
A. Parents/caregivers have access to financial support through Access 360™ and MedImmune. Tell them to visit MyAccess360.com to learn more.

Q. If I want to stop receiving information, can I opt out?
A. Yes, you can change your mind at any time and opt out of Cradle with Care. There are 3 ways to opt out: through the unsubscribe link located at the top and bottom of each email, through the return mailing address provided in all materials sent through the mail, or by calling the MedImmune Information line at 1-877-633-4411, Option 6. To cancel text message communications only, the parents/caregivers can reply using the word STOP.
Section 7: Summary
— Important Safety Information

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Section 7: Summary

Now that you’ve familiarized yourself with the process for SYNAGIS you should keep this guide in a convenient place and refer to sections individually as needed.

Don’t forget!

Severe RSV disease can have serious consequences for high-risk children⁶

As an SPP, you play an important role in ensuring that high-risk children receive all of their prescribed doses of SYNAGIS through RSV season

You are a key part of ensuring high-risk children receive adequate protection from RSV

LIMITATIONS OF USE
The safety and efficacy of SYNAGIS have not been established for treatment of RSV disease.

Please see page 38 for additional Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Important Safety Information

- SYNAGIS is contraindicated in children who have had a previous significant hypersensitivity reaction to SYNAGIS.
- Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to SYNAGIS. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to SYNAGIS. The relationship between these reactions and the development of antibodies to SYNAGIS is unknown. If a significant hypersensitivity reaction occurs with SYNAGIS, its use should be permanently discontinued. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of SYNAGIS.
- As with any intramuscular injection, SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder.
- Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays.
- Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count <50,000/microliter) and injection site reactions have been reported.

INDICATION
SYNAGIS is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:
- with a history of premature birth (≤35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season.
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season.
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season.

LIMITATIONS OF USE
The safety and efficacy of SYNAGIS have not been established for treatment of RSV disease.

DOsing
The recommended dose of SYNAGIS is 15 mg/kg of body weight given monthly by intramuscular injection. The first dose of SYNAGIS should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season.
The efficacy of SYNAGIS at doses less than 15 mg/kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

Please see accompanying full Prescribing Information, including Patient Information.
Section 8: Glossary

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
Glossary

Biologics
Biologics are medical products such as a vaccine, blood or blood component, allergenic, somatic cell, gene therapy, tissue, recombinant therapeutic protein, or living cells that are used as therapeutics to treat diseases. Biologics are isolated from a variety of natural sources – human, animal, or microorganism and may be produced by biotechnology methods and other cutting-edge technologies.14

Carve-outs
A payer strategy in which a payer separates ("carves-out") a portion of the benefit, such as behavioral health, and hires a managed care organization (MCO) to provide these benefits. This permits the payer to create a separate health benefits package, and assume greater control of their costs. Many health maintenance organization and insurance companies adopt this strategy because they do not have in-house expertise related to behavioral health or the service “carved out.” Other carve-out services may include cardiac, rehab and ambulatory.14

Claims review
The method by which an enrollee’s healthcare service claims are reviewed prior to reimbursement. The purpose is to validate the medical necessity of the provided services and to be sure the cost of the service is not excessive.14

Coinsurance
Coinsurance is the patient’s financial liability or the amount of money paid out of pocket by plan members for medical services. Coinsurance payments usually constitute a fixed percentage of the total cost of medical service covered by the plan. If a health plan pays 80% of a physician’s bill, the remaining 20%, which the member pays, is referred to as co-insurance.14

Coinsured
Any arrangement whereby coverage under a benefit involves the member’s financial responsibility on a proportional basis, i.e., percent of cost or charges.14

Copayment
A flat amount paid by the member when filling a prescription through a pharmacy. The balance of the cost for the prescription is covered by the health plan.14

Coordination of Benefits (COB)
A system whereby responsibility for claims is determined for a person who is covered by multiple insurers. Under this system, each person with multiple coverage has a primary and secondary insurer based on a set of industry rules. COB rules are designed to prevent duplicate payments for the same service.14

Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.
**Cost sharing**

The general set of financing arrangements whereby the consumer must pay out-of-pocket to receive care, either at the time of initiating care, or during the provision of healthcare services, or both. This includes deductibles, coinsurance and copayments, but not the share of the premium paid by the person enrolled.14

**Drug Utilization Review (DUR)**

Management of an insured population’s drug utilization. The goal of such management is to reduce the cost of drug therapies. Methods used include substitution of generic drugs for name brands, using a formulary to limit the universe of drugs that can be prescribed, use of co-payments for prescriptions, and encouraging the use of drugs that will trigger rebates or discounts.14

**Fee-for-service (FFS)**

Traditional provider reimbursement, whereby the physician or pharmacy is paid for the service performed.14

**Medicaid**

A federal program administered and operated individually by participating state and territorial governments that provides medical benefits to eligible low-income persons needing healthcare. The program costs are shared by the federal and state government. Medicaid also covers nursing-home care for the elderly.14

**Prior Authorization**

The process of obtaining any necessary approval under a specific payer’s Medical Management program before an approval for payment is issued.14

**Self insured**

The self-insured employer assumes risk for healthcare expenses in a plan that is self administered or through contract with a Third-Party Administrator (TPA); this form of coverage is regulated by the Employee Retirement Income Security Act of 1974 (ERISA).14
References


Please see page 38 for Important Safety Information and accompanying full Prescribing Information, including Patient Information.