

Synagis consensus criteria

A group of pediatricians and pediatric subspecialists from Idaho has met annually since August, 2006. These pediatricians decided to come together because they were vitally interested in prevention of RSV infection and ensuring access to Synagis (palivizumab) for high-risk infants during RSV season. Because Synagis is an expensive measure with challenging logistics for administration, cost-effective use was paramount in the minds of the pediatricians. The group sought to clarify criteria for use of Synagis, to define the season in the Intermountain West and Idaho, and to devise solutions to overcome obstacles to Synagis delivery.

I. RSV season

Synagis dosing should begin in late November to early December for most high-risk infants in most years. Preauthorization should be completed substantially earlier. Occasionally (less than one out of five seasons), local epidemiology services (see below in Logistics) will identify very early onset of RSV season and notify providers of an early RSV outbreak so that dosing can be initiated. Five monthly doses are expected to provide sufficient antibody levels for the RSV season (that is, dosing ends in March to April even if RSV season persists in May).

Historical data for RSV season from St. Luke's Regional Medical Center laboratory in Boise is attached. The onset of the season is defined as the first week with sustained RSV positive tests in consecutive weeks. In some but not all years, this definition of season onset is the same as the CDC definition of greater than 10% of tests positive for RSV. The end of the season requires three criteria: fall in numbers of RSV cases without subsequent increase, less than 10% of tests positive for RSV, and no new hospitalizations for RSV bronchiolitis.

Three epidemiology services advise local and regional providers on RSV activity:

- Salt Lake City, Utah (Intermountain Health Care and Primary Children's Hospital), accessed online <https://intermountain.net/portal/site/mdvsi/menuitem>
- Boise, Idaho (Idaho AAP Chapter in cooperation with St. Luke's Children's Hospital), accessed online <http://www.idahoAAP.org/monitor.htm>
- Idaho State Epidemiology Program, accessed online <http://healthandwelfare.idaho.gov/Health/DiseasesConditions/RSV/tabid/201/default.aspx>

Providers are encouraged to consult data from the geographically representative center in order to make decisions appropriate to their localities. Occasionally, the season differs between centers, and the timing of Synagis use should reflect the most geographically representative data.

II. Selection of high-risk infants

While new 2009 AAP guidelines have become available, the consensus group suggests that these need further review prior to change in recommendations. The evidence basis for the 2009 AAP guidelines remains forthcoming.

The consensus group supports the previous AAP criteria, which are similar in both 2006 and 2003 editions of *AAP Redbook: Report of the Committee on Infectious Diseases*, and in the publication *Pediatrics* 112:1442, 2003. The consensus group specified clarifications for high-risk infants for whom the AAP criteria do not fit well:

- Infants with airway anomalies who are less than 6 months old at the start of RSV season should receive Synagis irrespective of whether they were premature.
- AAP guidelines have indicated that two additional criteria are necessary for selection of infants born at 32-35 weeks prematurity who are less than 6 months old at the beginning of RSV season. The AAP criteria list childcare attendance, school-aged siblings, exposure to environmental air pollution, airway anomalies, and severe neuromuscular

disease. The consensus group proposes adding severe socioeconomic difficulties (no telephone, foster care, mentally retarded or otherwise impaired parents), multiple birth (twins, triplets, and higher), small for gestational age less than 10%ile, and Native American or Native Alaskan to this list; and cigarette smoke exposure appeared to qualify as environmental air pollution (a difference from interpretation by the AAP Committee on Infectious Diseases). The consensus group reinforced the standard that Synagis administration is not routine for infants greater than 32 weeks prematurity, and additional risk factors need to be considered for infants to qualify for Synagis administration.

- Infants with a variety of medical problems should be considered on a case-by-case basis, as it is not possible to make uniform recommendations with regard to immune deficiency, neurologic disease, cystic fibrosis, and other chronic respiratory diseases.
- The consensus group reinforces the statewide standard that Synagis dosing is not routinely given to children older than 24 months at the start of RSV season.
- For determining eligibility, the start of RSV season is interpreted as November 1 to allow uniform preauthorization in advance of the actual season onset for that year.

III. Logistics

Role of NICU/Special Care Nurseries: Maintain list of infants who received Synagis before discharge and infants for whom further Synagis dosing should be considered. Identify primary care clinic prior to discharge. Communicate the list of infants to primary care clinics by plans in discharge summary and by letters in the fall.

Role of primary care clinics: Make ultimate decision to order Synagis in view of risk factors and clinical status in the fall. Preauthorization may be completed by the specialty pharmacy that supplies Synagis to the primary care clinic, but some insurers require that the ordering physician submit the preauthorization. When indications for an infant do not automatically fit AAP guidelines, the ordering physician will need to provide support for a preauthorization, such as in the form of a letter.

Role of epidemiology services: Provide accessible updates on current RSV activity and when high-risk infants should be receiving doses. When there is an unusually early or late RSV season detected, changes are communicated to the patient care coordinators at the NICUs, to the specialty pharmacies providing Synagis, and to as many primary care clinics as possible.

Appeal of decisions in preauthorization: For denials of preauthorization that have been appealed, a statewide mechanism for review by a pediatric specialist practicing in Idaho (neonatologist, cardiologist, or infectious diseases pediatrician) should be established.

IV. Historical onset and end of RSV season in Boise, Idaho

RSV activity monitored at
St. Luke's Regional Medical Center Laboratory
Boise, Idaho

<u>Season</u>	<u>Onset</u>	<u>End</u>
2000-01	Jan 14	May 6
2001-02	Jan 13	May 12
2002-03	Jan 19	Apr 13
2003-04	Dec 21	Mar 28
2004-05	Jan 9	Apr 24
2005-06	Dec 11	Apr 10
2006-07	Jan 15	May 28
2007-08	Dec 31	May 5
2008-09	Dec 22	May 24

V. Contributors to consensus criteria:

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