

Notice to Providers: RSV Prophylaxis for 2011-2012 Season October 12, 2011

Dear Providers:

The UPHP Clinical Advisory Committee (CAC) and Pharmacy Clinical Advisory Committee (PCAC) both met recently and discussed immunoprophylaxis with Synagis®. During the 2010-11 season UPHP received requests for doses of Synagis® into April and May. This prompted a review to determine if the Upper Peninsula area displayed a geographic variability.

- The CDC surveillance data shows that Region 5 (Chicago) of which the Upper Peninsula is included had an onset later into November and the season duration was 21 weeks.
- Test results for aggregate data from the Marquette General Hospital lab noted that historically there were no positive test results in October or November and that positive tests decline in April.

The CAC discussion led to the recommendation that for this area, there is justification to delay in the initiation of prophylaxis until slightly later in the fall. Starting the 5 dose prophylaxis in late November would provide coverage into late April. An early December dose would provide coverage into early May. Historically, in April the number of positive tests wanes.

As in the past two years, UPHP authorization criteria have not mandated compliance with the AAP recommendations for Synagis® immunoprophylaxis in the 2009 Red Book¹ for the infants born at 32 weeks, to less than 35 weeks, gestation (32 weeks, 0 days through 34 weeks, 6 days) and less than 6 months of age at the start of the RSV season. Upon provider request, up to 5 doses will be allowed in this age group. The two factors that epidemiologic data suggest put infants at risk are a sibling younger than 5 years of age and attendance at child care with other infants or other young toddlers. These are the only two risk factors included in the prior authorization criteria.

We would also like to provide you with the following Synagis® immunity information provided by MedImmune.

- ❖ The targeted therapeutic threshold for Synagis® is ≥ 40 mcg/ml and this occurs within 48 hours following the initial IM injection. While a treated patient may drop below the 40 mcg/ml threshold before a second dose is due, (usually 25-30 mcg/ml) MedImmune data notes that in rat studies there was a 99% reduction in pulmonary RSV titers achieved with serum concentrations of 25-30 mcg/ml. With repeated monthly IM dosing, the mean serum trough concentration (day 30) remains above the desired target of ≥ 40 mcg/mL.^{2,3,4}

Please feel free to call the UPHP Pharmacy Department with any concerns you have regarding Synagis® administration or the prior authorization process. We will continue to monitor regional and local testing results at the beginning and end of the RSV season should you wish to call us for that information.

Information regarding prior authorization for the 2011-2012 season is as follows:

- ❖ The Synagis Prior Authorization form is available at www.uphp.com/Pharmacy . It utilizes the 2009 guideline.
- ❖ Coverage of up to five doses will be allowed for patients meeting gestational age requirements and with one of the two noted risk factors present if requested by the provider.
- ❖ A provider wishing to follow the 2006 guideline for infants born at 32 weeks, to less than 35 weeks, gestation (32 weeks, 0 days through 34 weeks, 6 days) may do so by indicating refills for 5 months and noting the infant is younger than 6 months of age at the start of the RSV season on the form.
- ❖ A MAXIMUM OF FIVE DOSES will be allowed per recipient. If a dose was administered in the inpatient setting, the date the dose was administered must be included on the request form.
- ❖ **Billing for Synagis® is processed through the pharmacy benefit directly to us from Walgreen's Specialty through Catalyst Rx.** You may bill ONLY for the RSV administration through the medical benefit.
- ❖ All Synagis® injections require prior authorization. There are NO EXCEPTIONS. Prior authorization is needed even if the child has a primary insurance other than UPHP.
- ❖ The Synagis® Prior Authorization Form is available at www.uphp.com/Pharmacy. You can also contact Catalyst Rx Customer Service or UPHP Customer Service to send the prior authorization form to you.
- ❖ Synagis® (palivizumab) will be processed through Catalyst Rx, our pharmacy benefit manager. Catalyst Rx **will use Walgreen's Specialty to supply Synagis®.** Walgreen's Specialty will call your offices to coordinate dosing and delivery of Synagis® once a request is approved by Catalyst Rx.

If you have questions regarding this process, please feel free to contact us directly.