Availability of Anti-RSV Immune Globulins

Customer Letter #2004-17

2004-09-24

Dear Customer:

This Customer Letter pertains to the following two MedImmune, Inc. products:

Synagis™ (palivizumab)
RespiGam® Respiratory Syncytial Virus Immune Globulin Intravenous (Human)

Availability for the 2004-2005 RSV season

CBS has been advised that Respigam® is no longer being manufactured by MedImmune, Inc. Once the current small stock of Respigam® in CBS' inventory is depleted, this product will no longer be available. Please note that during the 2003-2004 RSV season, CBS issued only a small number of vials of Respigam® to its hospital customers.

For the 2004-2005 respiratory syncytial virus (RSV) season, Canadian Blood Services will continue to make Synagis™ available for the prevention of RSV infection in children. Synagis™ and Respigam® are licensed by Health Canada and do not require Special Access Programme authorization.

Product Information

<table>
<thead>
<tr>
<th></th>
<th>Synagis™</th>
<th>RespiGam®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>MedImmune, Inc., Gaithersburg, Maryland</td>
<td>Genesis Biopharmaceuticals, Maryland</td>
</tr>
<tr>
<td>Contact for Information</td>
<td>Abbott Laboratories, 1-888-832-7755</td>
<td>1-800-828-6941</td>
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<tr>
<td>Description</td>
<td>Palivizumab - humanized monoclonal antibody directed to respiratory syncytial virus</td>
<td>Respiratory syncytial virus immune globulin intravenous (human)</td>
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<tr>
<td>Vial size</td>
<td>50 mg and 100 mg</td>
<td>2.5 gram</td>
</tr>
<tr>
<td>Licensure</td>
<td>Licensed by Health Canada and US FDA</td>
<td>Licensed by Health Canada and US FDA</td>
</tr>
</tbody>
</table>

Synagis™ will continue to be shipped directly from Abbott Laboratories and will not be stored at CBS sites. Synagis™ is available in both 100 mg and 50 mg vials.

The remaining stock of Respigam® will be distributed through CBS sites.
CBS Funding Criteria

During the 2003-2004 RSV season, the total cost for Synagis™ ordered through CBS was approximately $23 million. A course of treatment for the RSV season costs approximately $7000 - $9000 per patient. Each year a significant number of requests for Synagis™ are outside the CPS guidelines. As Synagis™ is an expensive product, CBS requires assurance that any request for Synagis™ outside of the CPS guidelines is medically justifiable.

In the provinces of British Columbia and Nova Scotia, a different approval process has been implemented for Synagis™ requests. Communications pertaining to the process in British Columbia and Nova Scotia will be issued separately to physicians by the Provinces of British Columbia, and Nova Scotia, respectively.

In all provinces/territories served by CBS (excluding British Columbia and Nova Scotia), Synagis™ will be funded by CBS for RSV prophylaxis of patients based on the categories recommended by the Canadian Paediatric Society (CPS):

- Children <24 months of age with bronchopulmonary dysplasia/chronic lung disease and who have required oxygen within the 6 months preceding the RSV season.
- Infants born prematurely at ≤32 weeks gestation and aged ≤ 6 months (with or without bronchopulmonary dysplasia), at the start of the RSV season.
- Children less than 2 years of age with hemodynamically significant cyanotic or acyanotic heart disease (requiring corrective surgery or on cardiac medication for hemodynamic considerations). Note: The specific diagnosis and/or cardiac medications must be provided with the request.)

These recommendations have been published in *Paediatrics & Child Health* 1999; 4(7): 474-80 (Reaffirmed February 2003) and *Paediatrics & Child Health* 2003; 8(10): 632:633.

To Request Synagis™

To facilitate processing orders for Synagis™ as quickly as possible, the requesting physician should use the attached Respiratory Syncytial Virus Prophylaxis Request Form (Version 09 2004).

Please note that the requesting physician must include their Provincial Medical License number on the Respiratory Syncytial Virus Prophylaxis Request Form (Version 09 2004).

Important:

Synagis™ requests not meeting the funding criteria described above ("Other" on the Respiratory Syncytial Virus Prophylaxis Request Form) must include the letters of support specified on the Form before they can be processed:

1. Letter from requesting physician providing medical justification for request and,
2. Letter from infectious disease specialist or respirologist supporting the request.
"Other" category requests received without the required supporting letters will be returned to the requesting physician and cannot be processed until the required supporting letters are received.

For all Synagis™ requests, the completed Request Forms (and supporting letters, if applicable) must be faxed to Abbott Laboratories as indicated below:

Abbott Laboratories Ltd.
Fax (514) 832-7251 or 1-800-513-7337

To Request Respigam®

Please contact your local CBS site to order RespiGam™. The enclosed Respiratory Syncytial Virus Prophylaxis Request Form (Version 09 2004) is not required to order RespiGam®. CBS sites will process hospital orders for RespiGam® according to normal ordering procedures.

Distribution of this Customer Letter and the Form

Hospital Blood Banks are requested to forward this Customer Letter and the enclosed Respiratory Syncytial Virus Prophylaxis Request Form (Version 09 2004) to their pediatric departments.

This Customer Letter and the Respiratory Syncytial Virus Prophylaxis Request Form (Version 09 2004) are also accessible on the CBS website (www.bloodservices.ca)

If you have questions about this CBS Customer Letter, please contact the CBS Fractionation Department at (613) 739-2392.

Sincerely,

Ms. Barbara Dickson
Director, Plasma Products
And Supply Management

Encl.
R:\Customer Letters\2004\Customer letter 2004-17 rsv letter.doc
RESPIRATORY SYNCYTIAL VIRUS PROPHYLAXIS REQUEST FORM

Patient Ref. # __________________________
Determined by Manufacturer

PATIENT INFORMATION

Patient Initials: ________________________

Birth Date: ______/_____/______

□ Male
□ Female

Present Weight: _______ g

Synagis™

Total # of 100 mg vials requested: ______
Total # of 50 mg vials requested: ______

Note: Dose is 15mg/kg, as per the package insert

PHYSICIAN INFORMATION (all fields mandatory)

Last Name: ____________________________

First Name: ____________________________

Institution Name: ______________________

Address: ______________________________

City: _________________________________ Province: __________________________ Province: __________________________ Postal Code: ____________

Telephone: ____________________________ Fax: ____________________________ Form completed by: __________________________ Name __________________________

Provincial Medical License # __________________________

Optional Field:

Medical specialty: __________________________

INDICATION FOR USE

□ Infants born prematurely at ≤32 weeks gestation and aged ≤6 months (with or without bronchopulmonary dysplasia), at the start of the RSV season.

Gestational Age: □ < 28 weeks □ 28-29 weeks □ 30-31 weeks □ 32 weeks

□ Patients < 24 months of age with bronchopulmonary dysplasia/chronic lung disease and who have required oxygen within the 6 months preceding the RSV season.

Age: □ ≤ 1 year old □ Between 1 and 2 years old

□ Children < 24 months of age with hemodynamically significant cyanotic or acyanotic congenital heart disease (requiring corrective surgery or on cardiac medication for hemodynamic considerations)

MANDATORY: Indicate specific diagnosis and/or cardiac medications __________________________

□ Other

Requires all of the following documentation before request can be processed:

1. Letter from requesting physician providing medical justification for request and,
2. Letter from infectious disease specialist or respirologist supporting the request

Shipping address (First dose, if different from above): ___________________________________________

Shipping address (Subsequent doses): ___________________________________________

Please fax this completed request form to:
Abbott Laboratories Ltd at (514) 832-7251 or at 1-800-513-7337