

Blood Programs Coordinating Office
Individual Eligibility Review Branch
Corporate and Direct Services Division

Bureau de coordination des programmes de sang
Direction de l'examen de l'admissibilité des cas individuels
Division des services directs et ministériels

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Dear Physician/Paediatic Unit:

RE: Process for Requesting Synagis™ (Palivizumab) in the 2007-2008 Respiratory Syncytial Virus (RSV) Season in the Province of Ontario

This letter provides instructions on how to make requests for Synagis™ in Ontario in the 2007-2008 Respiratory Syncytial Virus (RSV) season and supplements the Canadian Blood Services' Customer Letter #2007-33 (Availability of Synagis™ (Palivizumab)) dated September 27, 2007.

To request Synagis™ in the 2007-2008 RSV season physicians in Ontario must submit an 'Ontario Respiratory Syncytial Virus Prophylaxis Request Form' (version 09 2007- Ontario, see attachment). This request form is an interim measure for the 2007-2008 RSV season and must be used for all requests.

Additional copies of the request form are available from the Transfusion Ontario website at www.transfusionontario.org or by contacting Abbott Laboratories Ltd. at 1-888-832-7755.

Ontario physicians should **NOT** use the Respiratory Syncytial Virus Prophylaxis Request Form (version 09 2007) issued by the Canadian Blood Services.

Requests that Meet the Recommendations of the National Advisory Committee on Immunization (NACI)

Synagis™ will be funded by Canadian Blood Services for RSV prophylaxis of infants in Ontario if they meet one of these criteria:

- Infants born prematurely at ≤ 32 completed weeks gestation and aged ≤ 6 months at the start of, or during, the local RSV season; or
- Children < 24 months of age with bronchopulmonary dysplasia (BPD)/chronic lung disease (CLD) and who have required oxygen and/or medical therapy* within the 6 months preceding the RSV season; or
- Children < 24 months of age with hemodynamically significant cyanotic or acyanotic congenital 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.

*BPD/CLD medical therapies include: corticosteroids, bronchodilators, and diuretics specifically for the management of BPD/CLD.

These recommendations are in the 'Statement on the Recommended Use of Monoclonal Anti-RSV Antibody (Palivizumab)' that is from the Canadian Communicable Disease Report Volume 29 ACS-7, 15 September 2003. This is an Advisory Committee Statement of the National Advisory Committee on Immunization (NACI). The 2006 Canadian Immunization Guide, 7th Edition, also contains the guidelines for Respiratory Syncytial Virus prophylaxis by NACI. (www.naci.gc.ca).

The Ontario Provincial Advisory Group on RSV Immunoprophylaxis provided expert advice on the guidelines and procedures for the 2007-2008 RSV season.

Requests that Do Not Meet the Recommendations of NACI

Requests that do not meet the recommendations of NACI can still be submitted under the category 'Other'. These requests include:

- **Infants in the 33-35 Completed Weeks (33 weeks+ 0 days to 35 weeks + 6 days) Gestational Age Cohort and Aged ≤ 6 Months at the start/during the local RSV season and who live in isolated communities**

Requests for these infants must include the first 3 characters of the postal code of the patient on the request form. A completed Risk Assessment Tool is not required for these infants. An infectious disease specialist or a neonatologist or a respirologist does not need to provide a supporting letter.

- **Infants in the 33-35 Completed Weeks (33 weeks+ 0 days to 35 weeks + 6 days) Gestational Age Cohort and Aged ≤ 6 Months at the start/during the local RSV season**

Requests for these infants must include a completed Risk Assessment Tool (tool) signed by the requesting physician (see attachment). An infectious disease specialist or a neonatologist or a respirologist does not need to provide a supporting signature on the tool or a supporting letter. The first 3 characters of the postal code of the patient are not required on the request form.

Additional copies of the tool are available from the Transfusion Ontario website at www.transfusionontario.org or by contacting Abbott Laboratories Ltd. at 1-888-832-7755. The Risk Assessment Tool is an interim measure for the 2007-2008 RSV season.

- **Infants with a Special Diagnosis**

Requests for these infants must include a supporting letter from either an infectious disease specialist or a neonatologist or a respirologist. Neither the Risk Assessment Tool nor the first 3 characters of the postal code of the patient are required.

Sending Requests to Abbott Laboratories

To facilitate processing orders for Synagis™ quickly, the requesting physician should fax to Abbott the completed 'Ontario Respiratory Syncytial Virus Prophylaxis Request Form' for standard requests that meet the NACI recommendations. The Risk Assessment Tool should also be completed and faxed with the request form only for infants who are 33-35 completed weeks gestational age and do not live in isolated communities or do not have a special diagnosis. Supporting documentation should also be included if this is indicated above. The fax numbers of Abbott Laboratories are 514-832-7251 and 1-800-513-7337.

Requests that are submitted to Abbott Laboratories without the request form or the additional information/documentation, as indicated above, will be returned to the requesting physician. The request will be processed when all required documentation/information is submitted.

If you have questions about this letter, please contact the Blood Programs Coordinating Office at 416-326-6469 or 416-326-6477. If you have questions about Synagis™, please contact Abbott Laboratories Ltd. at 1-888-832-7755.

Yours sincerely,

Original signed by:
Thomas A. Smith
A/Manager