

Bulletin #775

November 6, 2009

## BENEFIT CHANGES TO NBPDP

This update to the New Brunswick Prescription Drug Program (NBPDP) Formulary is effective November 6, 2009.

### Included in this bulletin:

- **Special Authorization Additions**

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If you have any questions, please contact our office at 1-800-332-3691.

Yours truly,



Debbie LeBlanc  
New Brunswick Prescription Drug Program

## SPECIAL AUTHORIZATION ADDITIONS

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**Alendronate/cholecalciferol**  
(Fosavance®70/5600)  
70mg/ 140 µg tablets

1. For the treatment of osteoporosis:
    - with documented fragility fracture or;
    - without documented fractures in patients at high 10-year fracture risk
  2. For prophylaxis of corticosteroid induced osteoporosis in patients who will be or have been on systemic corticosteroid therapy for ≥ 3 months.
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**Solifenacin**  
(Vesicare®)  
5 mg and 10 mg tablets -  
resubmission

- For the treatment of overactive bladder with symptoms of urinary frequency, urgency and/or urge incontinence in patients who have not tolerated a reasonable trial of immediate-release oxybutynin.
  - Requests for the treatment of stress incontinence will not be considered.
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**Ustekinumab**  
(Stelara™)  
45 mg/0.5 mL vial for  
subcutaneous injection

- For patients with severe, debilitating chronic plaque psoriasis who meet all of the following criteria:
    - Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genital region;
    - Failure to respond to, contraindications to, or intolerant to methotrexate and cyclosporine;
    - Failure to respond to, intolerant to, or unable to access phototherapy
  - Initial approval limited to 16 weeks.
  - Continuation of therapy beyond 16 weeks will be based on response. Patients not responding adequately at these time points should have treatment discontinued with no further treatment with the same agent recommended.
  - An adequate response is defined as either:
    - ≥75% reduction in Psoriasis Area Severity Index (PASI) score from when treatment started, or
    - ≥50% reduction in PASI with a ≥5 point improvement in the Dermatology Life Quality Index (DLQI), or
    - A quantitative reduction in BSA affected with qualitative consideration of specific regions such as the face, hands, feet or genital region.
  - Must be prescribed by a dermatologist
  - Concurrent use of >1 biologic will not be approved
  - Approval limited to a dose of 45 mg administered initially at weeks 0, 4 and 16, then 45 mg every 12 weeks thereafter, up to a year (if response criteria met at 16 weeks).
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## SPECIAL AUTHORIZATION ADDITIONS

**Ranibizumab (Lucentis™)**  
2.3 mg / 0.23 mL vial for  
intravitreal injection

### Initial Coverage:

For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) where all of the following apply to the eye to be treated:

- Best Corrected Visual Acuity (BCVA) is between 6/12 and 6/96
- The lesion size is less than or equal to 12 disc areas in greatest linear dimension
- There is evidence of recent (< 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, or optical coherence tomography (OCT))
- Administration is to be done by a qualified ophthalmologist experienced in intravitreal injections.
- The interval between doses should not be shorter than 1 month.

Coverage will not be approved for patients:

- With permanent retinal damage as defined by the Royal College of Ophthalmology guidelines
- Receiving concurrent treatment with verteporfin.

### Continued Coverage:

Treatment with ranibizumab should be continued only in people who maintain adequate response to therapy.

Ranibizumab should be permanently discontinued if any one of the following occurs:

- Reduction in BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology
- Reductions in BCVA of 30 letters or more compared to either baseline and/or best recorded level since baseline as this may indicate either poor treatment effect, adverse events or both.
- There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.

The NBPDP will limit reimbursement to a maximum of 1 vial of ranibizumab per eye treated every 30 days. Claims submitted for greater than 1 vial, or submitted within 30 days of a previous claim will not be reimbursed.

### Pharmacy Claims:

Claims submitted by pharmacies for reimbursement of Lucentis should be billed **per vial**. This is an exception to the claims submission quantity standards outlined in the April 14, 2009 NBPDP Bulletin #749.

Lucentis is supplied by the manufacturer as a 2.3 mg/0.23 mL vial, however CPhA3 messaging for the online submission of pharmacy claims permits transmission of quantities to only one decimal place. Since the 0.23 mL vial cannot be adjudicated to two decimal places, this product should be claimed per vial.