

Q's and A's
Limited Use (LU) Process Changes
Effective September 27, 2005

Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary)
Limited Use Modernization Strategy

We are pleased to announce implementation of the next phase of the ministry's Limited Use modernization strategy. Effective September 27, 2005, two changes will occur to help improve the LU process for prescribers and pharmacists. These changes build on the initial phase which introduced the 'LU' intervention code on May 31, 2005 (please refer to BBS No. 531 posted May 17, 2005, and BBS No. 553 posted July 12, 2005). Information regarding changes to the LU process is also available from the Ontario Drug Benefit Program's website:

http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html

Limited Use Tripartite Committee

The Limited Use Tripartite Committee (LUTC), with representatives from the Drug Programs Branch (DPB), the Ontario Pharmacists' Association (OPA) and the Ontario Medical Association (OMA), have worked to identify opportunities to streamline the LU process, with the goal of reducing the administrative burden on physicians and pharmacists associated with LU prescriptions.

Elimination of the Limited Use Form

Effective with Edition No. 39 of the Ontario Drug Benefit (ODB) Formulary, on September 27, 2005, the requirement for the use of the ministry-issued LU prescription form has been discontinued. Thus, the prescriber will only need to document that the patient meets the LU criteria by writing the appropriate LU code [also called the Reason for Use (RFU) code] on a regular prescription form. Prescribers are encouraged to identify the LU code on the prescription by writing it as 'LU 123', or 'RFU 123'. This will help to differentiate the LU code from other numbers on the prescription.

For an initial transition period, prescribers with existing supplies of ministry-issued LU forms may continue to use them and order additional supplies from the ministry. The ministry-issued LU forms can be ordered until December 31, 2005, to allow practitioners time to transition to the use of regular prescriptions. After this date, practitioners may continue to use their existing LU forms until supplies are exhausted.

Eliminating the requirement to use the LU form will help physicians by streamlining prescribing procedures. The administrative burden of using two different prescription pads is removed.

It is noted that many pharmacies keep a separate file of copies of the LU forms. With the elimination of the LU form and the use of the 'LU' intervention code on initial LU claims, filing prescriptions with LU documentation (the 'LU prescription') with the regular prescriptions is adequate. With the use of the LU intervention code, it should be apparent where (i.e. on which claim) the initial LU prescriptions are filed.

Limited Use Expiry Dates

Also, effective with Edition No. 39 of the ODB Formulary, on September 27, 2005, some Limited Use (LU) drugs used in chronic conditions have been granted extended authorization periods beyond one year. Approximately 76 drugs will now have an indefinite authorization period (see list at end of this document). The updated Handbook of Limited Use Drug Products will also include details of which LU drugs have extended authorization periods. For these drugs, it is only necessary for the prescriber to confirm that the patient meets the LU clinical criteria by completing an LU prescription once. For other drugs that continue to have a defined LU authorization period, a new LU prescription must be completed according to the authorization period provided in the LU criteria (usually on an annual basis).

Implementing extended authorization periods for drugs used in certain chronic conditions will reduce the number of LU prescriptions written on an annual basis by approximately 50%.

Prescriptions with LU documentation must be kept on file at the pharmacy for two years after the claim is submitted and be available for auditing purposes during that time. Please be reminded that use of the 'LU' intervention code is mandatory when a new LU prescription is first filled.

Further enhancements to the HNS are planned to support the Limited Use process. We plan to continue to update you with further information in the future.

The following questions and answers are intended to address some situations that may arise:

Q1: What is the expiry date for existing Limited Use (LU) authorizations?

A1: As of September 27, 2005, for drugs with an indefinite LU authorization period, new LU forms dating back to May 31, 2005 are eligible, as long as the 'LU' intervention code was entered with the initial claim. All LU forms received prior to May 31, 2005, remain valid for one year from the date completed by the prescriber.

Q2: When is the 'LU' intervention code used?

A2: The 'LU' intervention code is to be used only when a new LU prescription or LU form is received. It is used by the HNS to track the presence, and the start date, of a new LU authorization

For more information about the LU intervention code, please refer to BBS No. 531 posted May 17, 2005, and BBS No. 553 posted July 12, 2005.

Q3: What happens if a prescription for an LU drug is transferred to another pharmacy?

A3: The receiving pharmacy must still obtain a copy of the LU prescription/form from the originating pharmacy, as per current policy. For drugs with an indefinite LU authorization

period, a copy of the LU prescription/form must be obtained only if the transfer occurs within the first two years of the authorization period. LU documentation must be retained for two years after the initial claim is submitted and is subject to audit during this time.

As a reminder, the receiving pharmacy must not enter the 'LU' intervention code. When the claim is submitted, the network will display the LU authorization effective date based on the original claim made by the originating pharmacy.

Q4: Where should LU documentation such as LU forms and LU prescriptions be filed?

A4: It is noted that many pharmacies keep a separate file of copies of the LU forms. With the elimination of the LU form, and with the use of the 'LU' intervention code on initial LU claims, filing LU prescriptions with the regular prescriptions is adequate. With the use of the 'LU' intervention code, it should be apparent where (i.e. on which claim) the initial LU prescriptions are filed. The choice of where to file LU prescriptions is up to the individual pharmacy. LU prescriptions must be kept on file at the pharmacy for two years after the claim is submitted and be available for auditing purposes during that time.

Q5: What happens if a patient presents a new LU prescription and there is already an LU authorization in place for the same drug and RFU?

A5: A new LU prescription creates a new authorization period, so the 'LU' intervention code must be entered when the prescription is filled. The network will then display the new LU authorization effective date.

Q6: What if the ministry changes the RFU and the patient still has a valid LU form?

A6: In situations where LU criteria have changed, prescribers must consider whether recipients meet the new criteria. If so, a new LU prescription must be completed within three months of the change in LU criteria. The 'grandparenting' RFU 279 may be used during the three-month period until a new LU prescription is received. The dispensing pharmacist cannot use the 'LU' intervention code with RFU 279. This RFU is only valid for claims submissions and is not to be used by prescribers on LU prescriptions.

Q7: When will the ministry-issued LU form be eliminated?

A7: The requirement to use the LU form will be discontinued effective September 27, 2005. Practitioners will be permitted to write the LU code [also called the Reason for Use (RFU) code] on a regular prescription.

The ministry will continue to accept orders for LU forms until December 31, 2005, to allow practitioners time to transition to the use of regular prescriptions. After this date, practitioners may use existing LU forms until supplies are exhausted.

Q8: For Plavix prescriptions, the Special Authorization Number (SAN) is pre-printed on the hospital's LU form. How will this be affected by the elimination of the LU form?

A8: Starting September 27, 2005, as with other LU drugs, LU documentation for Plavix may be written on a regular hospital prescription. The Special Authorization Number (SAN) that corresponds to the hospital where the patient was hospitalized must be submitted with the first Limited Use claim.

The ministry will continue to provide pre-printed LU forms to hospitals until December 31, 2005. Pharmacists may continue to obtain the SAN from the ODB website at: http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html. Lists with hospital SANs were also sent to all pharmacies with Update B to Edition No. 38 of the Formulary, which became effective September 4, 2003.

As a reminder, the 'LU' intervention code is not to be used with Plavix claims.

Q9: Are the LU forms which are preprinted with the SAN required for Vfend? Are there additional claim requirements for Vfend?

A9: The LU forms which are preprinted with the SAN may be used for Vfend until supplies are exhausted, but this is not a requirement. The RFU code for Vfend can be documented on a standard hospital prescription, or on a physician's regular prescription, as long as it is clearly documented from which hospital the patient was discharged. The initial Vfend claim also requires the 'LU' intervention code and a pharmacist identifier. Please refer to Q8 regarding Plavix for more information on the SAN list.

Q10: What other changes should I expect?

A10: Further program changes to the HNS are underway to enable the network to calculate and display the LU authorization expiry date. We will inform you when these changes are made.

The DPB continues to partner with the OMA and OPA to identify further options for improving the LU process. This is an ongoing process that will result in transition periods as incremental changes are implemented, and it is recognized that these changes may impact pharmacists and physicians in different ways. The individual organizations will provide supplemental communications to explain these changes, and will also provide support to address questions from physicians and pharmacists.

Q11: How do I get more information?

A11: In the next few weeks, watch for a BBS with further information about the LU process changes.

Please refer to the ODB website at:

http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html

Contact information:

Ontario Drug Benefit Program

5700 Yonge Street, 3rd Floor

Toronto, ON M2M 4K5

e-mail: drugprograms@moh.gov.on.ca

Tel: 416-327-8109, or toll-free 1-866-811-9893

Fax: 416-327-8123

ODB Help Desk: 1-800-668-6641

LU AUTHORIZATION EXPIRY DATES EFFECTIVE SEPTEMBER 27, 2005

INDEFINITE DURATION

Anticonvulsants gabapentin carbamazepine CR topiramate clobazam lamotrigine vigabatrin
Oncology – systemic tx anastrozole letrozole exemestane temozolomide fludarabine thyrotropin capecitabine clodronate etidronate interferon
BPH tamsulosin alfuzosin finasteride dutasteride
Cardiovascular ticlopidine pentoxifylline dipyridamole / ASA carvedilol midodrine ezetimibe furosemide
Psoriasis calcipotriol cyclosporine
Diabetes acarbose insulin lispro insulin lispro/ insulin lispro protamine insulin aspart
Pancreatic enzymes pancrelipase
Biliary cirrhosis / sclerosing cholangitis ursodiol ursodiol DS
Glaucoma latanoprost bimatoprost brimonidine dorzolamide brinzolamide travoprost dorzolamide/timolol

latanoprost/timolol brimonidine/timolol
Ophthalmic therapy (keratoconjunctivitis sicca) petrolatum / mineral oil polyvinyl alcohol products methylcellulose products
Osteoporosis alendronate risedronate raloxifene
Parkinson's disease levodopa/carbidopa entacapone
Asthma salmeterol salmeterol/fluticasone salbutamol formoterol ipratropium ipratropium/salbutamol nedocromil orciprenaline isoproterenol budesonide budesonide/formoterol fenoterol racemic epinephrine
Rheumatoid arthritis leflunomide cyclosporine
Organ transplant rejection mycophenolate sirolimus tacrolimus
Paget's disease etidronate risedronate 30mg
Urinary incontinence tolteridine
Lactose intolerance lactase
Antidepressants bupropion

1-YEAR DURATION

Cholinesterase inhibitors donepezil rivastigmine galantamine
COX-2 inhibitors celecoxib
Narcotic analgesics fentanyl codeine oxycodone meperidine
Low Molecular Weight Heparins (LMWH) dalteparin nadroparin tinzaparin enoxaparin fondaparinux
Antibiotics, antifungals ciprofloxacin levofloxacin moxifloxacin gatifloxacin ofloxacin (oral, ophthalmic) fusidic acid/sodium fusidate rifabutin linezolid fluconazole voriconazole
Antivirals ganciclovir famciclovir valganciclovir acyclovir valacyclovir oseltami vir
Oncology – systemic tx cladribine
Oncology – supportive tx dolasetron granisetron ondansetron tetrahydrocannabinol benzydamine
Cardiovascular clopidogrel
Acne vulgaris tretinoin
Atopic dermatitis pimecrolimus tacrolimus
Topical scabicide permethrin

Proton pump inhibitors omeprazole pantoprazole lansoprazole Hp-PAC
HRT (all LU products) estraderm 50/estragest all estradiol 17B products norethindrone/estradiol 17B
Asthma Montelukast
Testosterone replacement Testosterone
Antidiarrheals loperamide diphenoxylate/atropine
Strabismus/Cervical dystonia Botulinum toxin
Management of Subarachnoid Hemorrhage Nimodipine
Migraine therapy Flunarazine
Allergic rhinitis ipratropium nasal spray

5-YEAR DURATION

Oncology anagrelide