



Australian Government

Department of Health

PBS Arrangements for medicines for the treatment of paroxysmal nocturnal haemoglobinuria

1 March 2022

Commencing 1 March 2022 Soliris® (eculizumab) and Ultomiris® (ravulizumab) will be listed on the Pharmaceutical Benefits Scheme (PBS) Section 100 Highly Specialised Drugs (HSD) program for the treatment of paroxysmal nocturnal haemoglobinuria (PNH) under certain conditions.

Access to Soliris® under the Life Saving Drugs Program (LSDP) will be ceased for new patients from 1 March 2022. To ensure patient access to this drug is maintained for patients currently undergoing treatment while access is transitioned to the PBS Section 100 HSD program, there will be transitional arrangements in place with the sponsor company, Alexion Pharmaceuticals Australasia Pty Ltd (Alexion). For further details of these arrangements for existing and new patients please contact Alexion at: medicalinformation.australasia@alexion.com or call 1800 788 189

Information for Prescribers

To assist prescribers in selecting the most appropriate PBS item code to commence their patient on PBS Section 100 HSD-subsidised treatment, a table summarising the eligible patient groups according to the available treatment phases and their corresponding item codes is available below.

Prescribers should select the item code based on whether their patient has previously accessed Soliris® through the LSDP or whether they have accessed either Soliris® or Ultomiris® through clinical trials, managed access programs or through other private arrangements. Correct selection is important to ensure appropriate quantities are authorised to complete an uninterrupted induction phase or continue maintenance treatment.

Prescribers should also be aware of the additional eligibility criteria that applies for PBS Section 100 HSD-subsidised access to Soliris® and Ultomiris®. The criteria largely align with the existing eligibility criteria for LSDP-funded access and must be met for access to these medicines through the PBS. Please note that greater compliance activities will apply for this listing. Full details of all eligibility criteria can be found by entering the selected item code into the search bar on the PBS website at: www.pbs.gov.au.

Applications for authority to prescribe either Soliris® or Ultomiris® must be submitted to Services Australia either online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos or via post. Applications may be mailed to:

Services Australia
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

PBS Item Codes and Eligible Patient Groups

Eculizumab		
Item Code	Treatment Phase	Patient group
12840T (Public)	Initial treatment – Initial 1 (new patient) induction doses	Patients who have not received prior treatment with eculizumab for PNH.
12896R (Private)		
12900Y (Public)	Balance of Supply (transition from non-PBS-subsidised treatment during induction phase)	Patients who have received non-PBS treatment with eculizumab for PNH prior to 1 March 2022 The patient must have received insufficient quantity to complete the induction treatment phase Non-PBS-subsidised treatment includes access through LSDP, clinical trials or other private arrangements
12864C (Private)		
12877R (Public)	Initial treatment – Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)	Patients who are pregnant or planning pregnancy The patient must have received PBS-subsidised treatment with ravulizumab for PNH
12899X (Private)		
12877R (Public)	Grandfather 1 (transition from non-PBS-subsidised treatment) – maintenance phase	Patients who have received non-PBS-subsidised eculizumab for PNH prior to 1 March 2022 and have completed the induction treatment phase Non-PBS-subsidised treatment includes access through clinical trials or other private arrangements
12899X (Private)		
12877R (Public)	Grandfather 2 (transition from LSDP-funded eculizumab)	Patients who have previously received eculizumab through the LSDP, and completed the induction phase treatment
12899X (Private)		
12877R (Public)	First Continuing Treatment	Patients who have received PBS-subsidised treatment with eculizumab for PNH under an 'Initial' or 'Grandfather' treatment criteria
12899X (Private)		
12877R (Public)	Subsequent Continuing Treatment	Patients who have previously received PBS-subsidised treatment with eculizumab for PNH under the 'First Continuing Treatment' or 'Switch' criteria
12899X (Private)		

Ravulizumab			
Item Code 300mg/3mL	Item Code 1.1g/11mL	Treatment Phase	Patient group
12898W (Public)	12856P (Public)	Initial treatment – Initial 1 (new patient) induction dose	Patients who have not received prior treatment with ravulizumab for PNH
12841W (Private)	12901B (Private)		
12898W (Public)	12856P (Public)	Initial treatment – Initial 2 (switch from LSDP eculizumab) induction dose	Patients who have received eculizumab for the treatment of PNH through LSDP and wish to switch to ravulizumab
12841W (Private)	12901B (Private)		
12898W (Public)	12856P (Public)	Return from PBS-subsidised eculizumab – induction dose	Patients who are returning to treatment with ravulizumab following pregnancy. Patients will have received prior PBS-subsidised treatment with eculizumab through the ‘Initial treatment – Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)’ criteria
12841W (Private)	12901B (Private)		
12884D (Public)	12883C (Public)	Grandfather (transition from non-PBS-subsidised treatment)	Patients who have received non-PBS- subsidised treatment with ravulizumab for PNH prior to 1 March 2022
12895Q (Private)	12897T (Private)		
12884D (Public)	12883C (Public)	First Continuing Treatment	Patients who have received PBS- subsidised treatment with ravulizumab for PNH under an ‘Initial’ or ‘Grandfather’ treatment criteria
12895Q (Private)	12897T (Private)		
12884D (Public)	12883C (Public)	Subsequent Continuing Treatment	Patients who have previously received PBS-subsidised treatment with ravulizumab for PNH under the ‘First Continuing Treatment’ or ‘Return’ criteria
12895Q (Private)	12897T (Private)		

Information for pharmacists

Pharmacists should note that Soliris® is currently also listed on the PBS Section 100 HSD program for the treatment of atypical haemolytic uraemic syndrome (aHUS). When dispensing, attention must be paid to the selection of the correct PBS item code to ensure the correct product, under the correct program (public or private), for the correct indication is claimed. Applying incorrect item codes may result in a rejection warning message from Services Australia.

For new patients prior to 1 March 2022, the medicines sponsor has made transitional arrangements for supply until the treating physician is able to make arrangements for access under the PBS Section 100 HSD program. Treating physicians or pharmacists can contact Alexion to discuss access arrangements for these patients.

Information for consumers

For existing LSDP patients receiving subsidised treatment, we recommend that patients seek an appointment with their treating physician to discuss transitioning to the PBS Section 100 HSD arrangements prior to 1 March 2022. So that the necessary arrangements for a new prescription can be made, the LSDP will continue to supply eculizumab for existing patients until they are able to transition up (or up to 31 May 2022, whichever occurs first). This will ensure the treatment regimen can continue without interruption.

Those who receive a PBS Section 100 HSD authority prescription from their treating physician, for either Soliris® or Ultomiris®, will be able to access their medicines at the standard PBS-subsidised co-payment price set each calendar year. For 2022, the cost for general patients is \$42.50 and for concession card holders is \$6.80

For new patients requiring treatment prior to 1 March 2022, the medicines sponsor has made transitional arrangements for supply until the treating physician is able to make arrangements for access under the PBS Section 100 HSD program listing. Patients may wish to discuss these transitional access arrangements with their treating physician or pharmacist.