# SCHEDULE OF PHARMACEUTICAL BENEFITS EFFECTIVE 1 APRIL 2024 ERRATA

**(1)** This Erratum removes the Premium for Copaxone brand of **Glatiramer Acetate** in the 1 April 2024 Schedule.

## ▪ GLATIRAMER ACETATE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL syringes and pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL pen devices are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**
***7695***
Multiple sclerosis
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**
***6860***
Multiple sclerosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices**

13110B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 668.10 | 31.60 | [a] Copaxone [TB] |

(2) This Erratum corrects the restrictions for Niraparib in the 1 April 2024 Schedule.

Adding or deleting the words “up to” from the treatment phase. These changes appear in both treatment phases: Initial and Continuing treatment with/without BRCA 1/2 gene. The corrected treatment phases read as follows:
14088L - “Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules”
13089X - “Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules”
14094T - “Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules."
13079J - “Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules”.

## ▪ NIRAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

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**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

**Clinical criteria:**

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

**niraparib 100 mg capsule, 56**

14088L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 6636.97 | 31.60 | Zejula [GK] |
| 1 | 2 | .. | 9874.39 | 31.60 | Zejula [GK] |

## ▪ NIRAPARIB

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Class 5 - Pathogenic
Class 4 - Likely pathogenic
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**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

**Clinical criteria:**

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**niraparib 100 mg capsule, 56**

13089X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | .. | 6636.97 | 31.60 | Zejula [GK] |

## ▪ NIRAPARIB

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**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

### niraparib 100 mg capsule, 56

14094T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 6636.97 | 31.60 | Zejula [GK] |
| 1 | 5 | .. | 9874.39 | 31.60 | Zejula [GK] |

## ▪ NIRAPARIB

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**Note** Special Pricing Arrangements apply.

**Authority required**

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules

**Clinical criteria:**

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

### niraparib 100 mg capsule, 84

13079J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | .. | 9874.39 | 31.60 | Zejula [GK] |

**(3)** This Erratum reverses the priced reduction for item code 10345L, DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE in the 1 April 2024 Schedule.

## ▪ DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE

**Authority required (STREAMLINED)**

***9981***

HIV infection

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

***10116***

HIV infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30**

| 10345L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | .. | *1439.59 | 31.60 | Triumeq [VI] |