RETHINK WHAT'S POSSIBLE...

ZYDELIG®
(idelalisib)

PBS LISTED[1]
1st September 2017

ZYDELIG – a first-in-class oral PI3Kδ inhibitor – is PBS listed from 1st September 2017 for the treatment of:

- **Double-refractory FL*[2]**

  *As monotherapy for the treatment of patients with FL which is refractory to at least two prior systemic therapies. The disease must be refractory to rituximab and an alkylating agent.[2]

- **Relapsed CLL or SLL†[2]**

  †In combination with rituximab for the treatment of adult patients with CLL or SLL upon relapse in patients for whom chemo-immunotherapy is not considered suitable.[2]

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Double-refractory FL PBS criteria[1]

The condition must be refractory to a prior therapy with rituximab

AND

The condition must be refractory to a prior therapy with an alkylating agent

AND

The treatment must be the sole PBS subsidised drug for this condition.

- The condition is considered refractory to a prior therapy when the patient experiences less than a partial response **or** progression of disease within 6 months after completion of the prior therapy.
- The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

The initial authority application must be made in writing and must include:

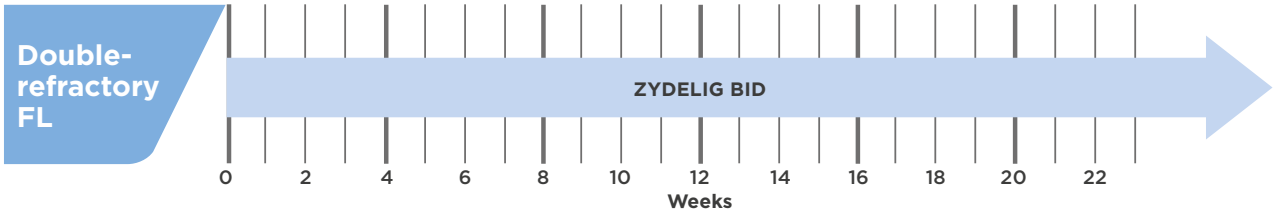
- A completed authority prescription form; and
- A completed Refractory follicular B-cell non-Hodgkin's lymphoma PBS Authority Application – Supporting information form which must include date of completion of prior therapies with rituximab and an alkylating agent

Refer to PBS website (http://www.pbs.gov.au/) for details on where to submit applications. Applications for continuing treatment are made via phone by contacting the Department of Human Services.

Recommended dosing: Double-refractory FL

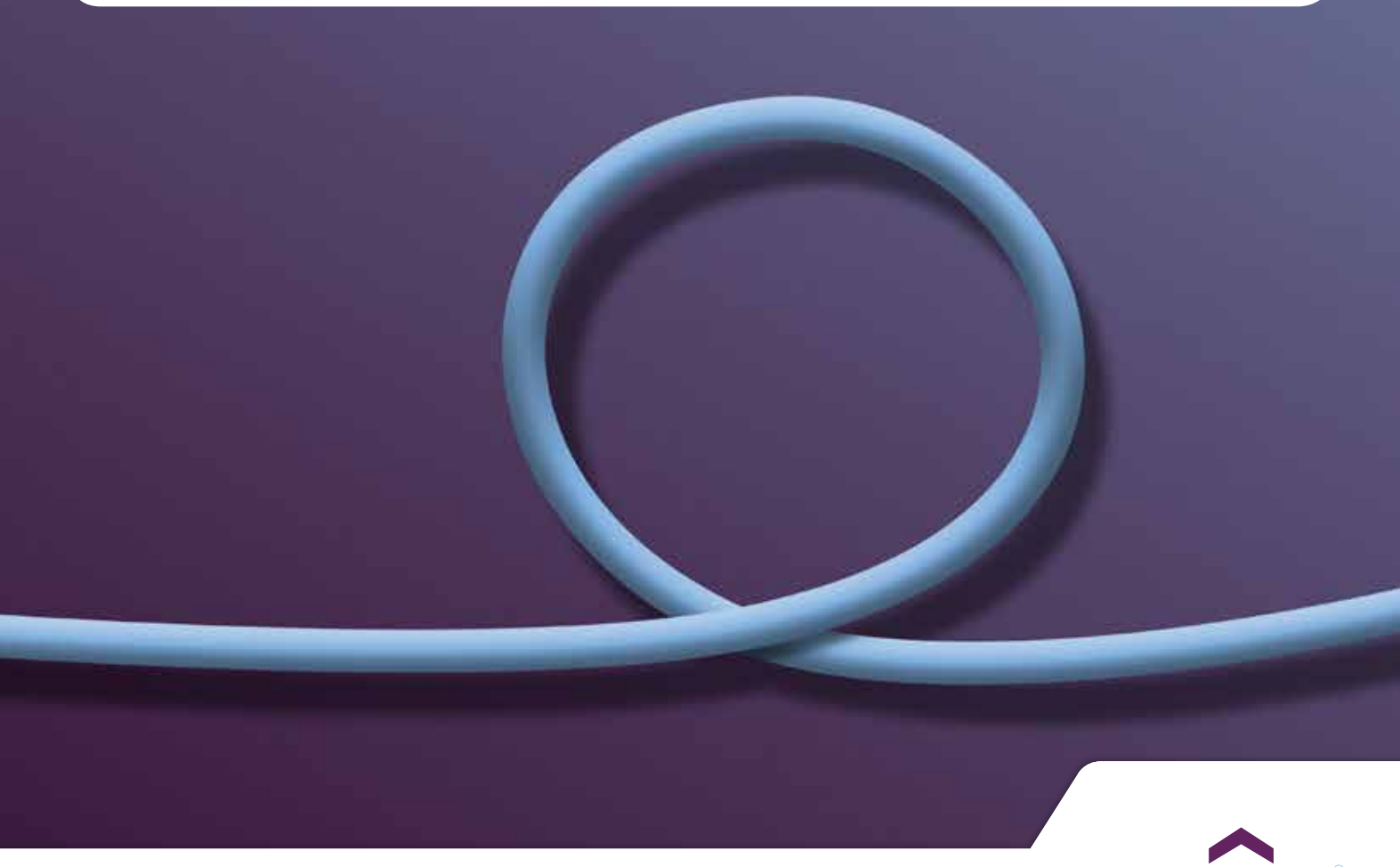
- ZYDELIG 150 mg BID

FL recommended dosing



Information for FL prescribing

ZYDELIG presentation[1]	PBS code	Maximum quantity	Maximum repeats
Tablet, 150 mg, 60 tablets	11165P	1	5
Tablet, 100 mg, 60 tablets	11171Y	1	5



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Relapsed CLL or SLL PBS criteria[1]

The patient must not have previously received PBS subsidised treatment with this drug

AND

The treatment must be in combination with rituximab

AND

The condition must have relapsed or be refractory to at least one prior therapy

AND

The condition must be CD20 positive

AND

Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage)

AND

Patient must be inappropriate for chemo-immunotherapy.

The initial authority application must be made in writing and must include:

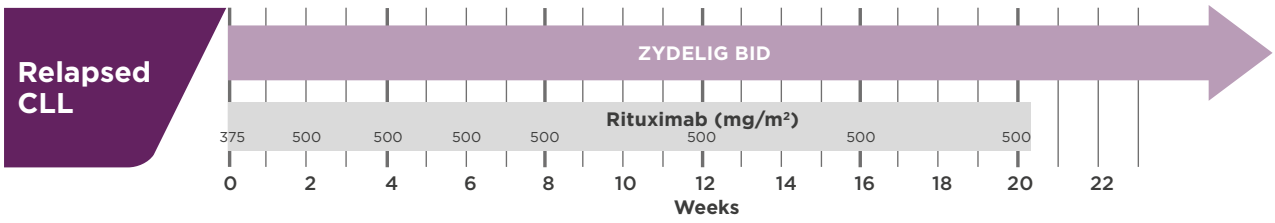
- A completed authority prescription form; and
- A completed CLL/SLL PBS Authority Application – Supporting information form; and
- Pathology report (full blood count no more than one month old) indicating that the patient can be considered inappropriate for chemo-immunotherapy due to one or more of the following:
  - Recent severe neutropenia (ANC ≤ 1.0 x 10^9/L); or
  - Recent severe thrombocytopenia (platelet count ≤ 50 x 10^9/L); or
  - Presence of 17p chromosomal deletion using FISH.

Refer to PBS website (http://www.pbs.gov.au/) for details on where to submit applications. Applications for continuing treatment are made via phone by contacting the Department of Human Services.

Recommended dosing: Relapsed CLL/SLL

- ZYDELIG 150 mg BID + rituximab intravenous 375 mg/m² on week 0, then 500 mg/m² on weeks 2, 4, 6, 8, 12, 16, 20

CLL/SLL recommended dosing



Information for CLL/SLL prescribing

ZYDELIG presentation[1]	PBS code	Maximum quantity	Maximum repeats
Tablet, 150 mg, 60 tablets	11162L	1	5
Tablet, 100 mg, 60 tablets	11170X	1	5
Rituximab presentation[1]*	**Streamlined authority code**	**Maximum amount**	**Maximum repeats**
Injection, 100 mg/10mL, 2 x 10 mL	7040	1100 mg	5
Injection, 500 mg/50mL, 1 x 50 mL	7040	1100 mg	5

Detection of deletion 17p by FISH	MBS code
Detection of 17p chromosomal deletions by FISH, in a patient with relapsed or refractory CLL or SLL, on a peripheral blood or bone marrow sample, requested by a specialist or consultant physician, to determine if the requirements for access to ZYDELIG on the Pharmaceutical Benefits Scheme are fulfilled.	73343

*Refer to rituximab Product Information before prescribing.

Zydelig® (idelalisib)

Resources for you and your patients

Clinical resource for physicians

This clinical resource has been developed to assist healthcare professionals in the management of patients prescribed ZYDELIG. It provides an overview of recommendations for monitoring, prophylaxis, dose interruption and symptomatic management of adverse events associated with ZYDELIG. Refer to the Product Information for further information.

Navigate patient pack

This pack has been developed to help answer questions commonly asked by people being treated with ZYDELIG. It contains an information booklet covering various aspects of treatment, including an overview of the patient's condition, how ZYDELIG works, and what to expect from treatment. The pack also contains a treatment diary for patients to keep record of any side effects while on treatment and a wallet card.

FL: follicular lymphoma; CLL: chronic lymphocytic leukaemia; SLL: small lymphocytic lymphoma; ANC: absolute neutrophil count; FISH: fluorescence in situ hybridisation.

From 1st September 2017

PBS Information: CLL/SLL & FL. Written authority required.
Refer to PBS Schedule for full authority benefit information.

PLEASE REVIEW PRODUCT INFORMATION BEFORE PRESCRIBING. **PLEASE REFER TO THE BOXED WARNING IN THE PRODUCT INFORMATION.** TO HAVE A COPY OF THE PRODUCT INFORMATION SENT TO YOU, TELEPHONE GILEAD SCIENCES ON 1800 806 112, OR IT CAN BE ACCESSED VIA THE TGA WEBSITE (HTTPS://WWW.EBS.TGA.GOV.AU).

Minimum Product Information ZYDELIG® (idelalisib) 100 mg and 150 mg Tablets. INDICATIONS: In combination with rituximab or ofatumumab for CLL/SLL upon relapse in patients where chemo-immunotherapy is unsuitable. Monotherapy treatment of FL refractory to at least two prior systemic therapies (disease must be refractory to both rituximab and an alkylating agent). **DOSAGE AND ADMINISTRATION:** 150 mg twice daily. Dose modification may be required. **CONTRAINDICATIONS:** hypersensitivity. **PRECAUTIONS: Serious Infections**: treatment should not be initiated with any evidence of systemic bacterial, fungal or viral infections. Serious and fatal infections including PJP and CMV have occurred. Administer prophylaxis for PJP to all patients throughout Zydelig treatment and for 2-6 months after discontinuation, based on clinical judgement. Assess CMV status prior to initiating treatment. At least monthly monitoring for CMV is recommended in patients with positive CMV serology at baseline or other evidence of a history of CMV infection or disease. Patients with signs of infection should be promptly treated. **Hepatotoxicity:** monitoring required. **Hepatitis Infection and Reactivation:** prior screen for HBV and HCV. **Diarrhoea/Colitis:** assessment of hydration and dose interruption should be considered in severe cases. Infectious causes should be considered when assessing colitis. **Pneumonitis:** Dose interruption should be considered with any severity of symptomatic pneumonitis. Infectious causes should be considered when assessing pneumonitis. Immunisation: Vaccination prior to treatment of patients at substantial risk of an infection. Neutropenia, **Anaemia, Lymphopenia and Thrombocytopenia:** Grade 3 or 4 neutropenia including febrile neutropenia have occurred. Monitor bloods at least every 2 weeks for the first 6 months, weekly while absolute neutrophil count is < 1.0x109 /L. Absence of neutropenia does not exclude immunosuppression and risk of serious infection. **Severe Cutaneous Reactions:** life threatening (Grade ≥ 3) cutaneous reactions have been reported. Fatal cases of SJS-TEN have occurred when patients were treated with Zydelig when administered concomitantly with other medications associated with SJS-TEN. Treatment should be interrupted immediately if SJS or TEN is suspected and permanently discontinued where there is a case of severe cutaneous reaction. **Intestinal Perforation:** discontinue permanently. **Progressive Multifocal Leukoencephalopathy:** diagnosis should be considered with new onset of, or changes in pre-existing neurologic signs and symptoms. **Transient Lymphocytosis.** Effects on Fertility: highly-effective contraception during and 1 month after. Pregnancy (Cat. D). Lactation. Children (<18 years), refer to full PI. **INTERACTIONS WITH OTHER MEDICINES:** Effects of other drugs on Zydelig: CYP3A Inducers (rifampin, phenytoin, St. John's Wort, or carbamazepine). CYP3A Inhibitors (ketoconazole). **Effects of Zydelig on other drugs:** CYP3A Substrates (alfentanil, cyclosporine, sirolimus, tacrolimus, cisapride, pimozide, fentanyl, quinidine, ergotamine, dihydroergotamine, midazolam, certain antiarrhythmics, calcium channel blockers, benzodiazepines, HMG-CoA reductase inhibitors, phosphodiesterase-5 (PDE5) inhibitors, and warfarin), refer to full PI. **ADVERSE EFFECTS:** Diarrhoea, nausea, constipation, abdominal pain, vomiting, gastroesophageal reflux disease, stomatitis, headache, lethargy, fatigue, pyrexia, peripheral oedema, chills, asthenia, rash, night sweats, pruritus, pneumonia, neutropenia, anaemia, thrombocytopenia, cough, dyspnoea, muscle spasms, sepsis, sinusitis, urinary tract infection, bronchitis, oral herpes, arthralgia, decreased appetite, weight decreased, dehydration, hypokalaemia, alanine aminotransferase increased, aspartate aminotransferase increased, insomnia. **This is not the full Product Information. Please review the full Product Information before prescribing. Product Information is available on request from Gilead Sciences Pty Ltd (PH: 1800 806 112).** Date of preparation 14 March 2017.

References: 1. Pharmaceutical Benefits Schedule. Available at: www.pbs.gov.au. **2.** Zydelig Product Information, 1 February 2017.

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ZDG/AU/17-08/MI/1521 Prepared September 2017. GIL0120

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