Maklumat tambahan indikasi
Year 2020
Products Approved For Additional Indication (DCA 349 – 1 Oktober 2020)

	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Humira Solution for Injection in Prefilled syringe 80mg/0.8ml** [Adalimumab 80mg/0.8mL] 1.2 **Humira Solution for Injection in Prefilled Pen 80mg/0.8ml** [Adalimumab 80mg/0.8mL] 1.3 **Humira Solution for Injection in Pre-filled syringe 40mg/0.4ml** [Adalimumab 40mg/0.4mL] 1.4 **Humira Solution for Injection in Pre-filled Pen 40mg/0.4ml** [Adalimumab 40mg/0.4mL]	➢ Indication: *Adolescent hidradenitis suppurativa* *Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy.* ➢ Posology: ***Adolescent hidradenitis suppurativa*** *There are no clinical trials with Humira in adolescent patients with hidradenitis suppurativa (HS). The posology of Humira in these patients has been determined from pharmacokinetic modeling and simulation.* *The recommended Humira dose in adolescent patients from 12 years of age weighing at least 30 kg with hidradenitis suppurativa is 80 mg at Week 0 followed by 40 mg every other week starting at Week 1 via subcutaneous injection.* *Humira may be available in different strengths and/or presentations.* *In adolescent patients with inadequate response to Humira 40 mg every other week, an increase in dosage to 40 mg every week or 80 mg every other week may be considered.* *Antibiotics may be continued during treatment with Humira if necessary. It is recommended that the patient should use a topical antiseptic wash on their HS lesions on a daily basis during treatment with Humira.*	**ABBVIE SDN BHD** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort 47410 Petaling Jaya, Selangor

		Continued therapy beyond 12 weeks should be carefully reconsidered in a patient with no improvement within this time period. *Should treatment be interrupted, Humira may be re-introduced as appropriate.* *The benefit and risk of continued long-term treatment should be periodically evaluated.* *There is no relevant use of Humira in children aged less than 12 years in this indication.*	
2.	2.1 **Venclexta Tablet 10mg** [Venetoclax 10mg] 2.2 **Venclexta Tablet 50mg** [Venetoclax 50mg] 2.3 **Venclexta Tablet 100mg** [Venetoclax 100mg]	➢ *Indication:* *VENCLEXTA in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated CLL.* ➢ Posology: *<u>Venclexta in Combination with Obinutuzumab</u>* *Venclexta should be given for a total of 12 cycles: each cycle consisting of 28 days: 6 cycles in combination with obinutuzumab, followed by 6 cycles of Venclexta as a single agent.* *On Cycle 1 Day 1, start obinutuzumab administration at 1000 mg (dose may be split as 100 mg and 900 mg on Day 1 and 2, respectively). Administer 1000 mg on Day 8 and 15 of Cycle 1, and on Day 1 of five subsequent cycles (total of 6 cycles).* *On Cycle 1 Day 22, start Venclexta according to the ramp-up schedule (see Table 1), continuing through Cycle 2 Day 28. After completing the ramp-up schedule, patients should continue Venclexta 400 mg once daily from Cycle 3 Day 1 of obinutuzumab to the end of Cycle 12.*	**ABBVIE SDN BHD** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort 47410 Petaling Jaya, Selangor