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Year 2015
Products Approved For Additional Indication (DCA 294 – 22 Disember 2015)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Gadovist 1.0mmol/ml Solution for Injection** [Gadobutrol]	➢ Indication: *This medicinal product is for diagnostic use only.* *Gadovist is indicated in adults and children of all ages (including term neonates) for:* • *Contrast enhancement in cranial and spinal magnetic resonance imaging (MRI).* *Gadovist is particularly suitable for cases where the exclusion or demonstration of additional pathology may influence the choice of therapy or patient management for detection of very small lesions and for visualization of tumours that do not readily take up contrast media.* *Gadovist is also suited for perfusion studies for the diagnosis of stroke, detection of focal cerebral ischaemia and tumour perfusion.* • *Contrast enhanced MRI of liver or kidneys in patients with high suspicion or evidence of having focal lesions to classify these lesions as benign or malignant.* • *Contrast enhancement in Magnetic Resonance Angiography (CE-MRA).* *Gadovist can also be used for MR Imaging of pathologies of the whole body.* *It facilitates visualisation of abnormal structures or lesions and helps in the differentiation between healthy and pathological tissue.* ➢ Posology: *Special patient populations*	**BAYER CO. (MALAYSIA) SDN. BHD.** T1-14 Jaya 33, No.3, Jalan Semangat, Seksyen 13, 46200 Petaling Jaya, Selangor

		Pediatric population *For children of all ages including full-term newborns, the recommended dose is 0.1mmol gadobutrol per kg body weight (equivalent to 0.1ml Gadovist per kg body weight) for all indications.*	
2	2.1 **Eylea 40mg/ml Solution for Injection in Prefilled Syringe** [Aflibercept 40mg/ml] 2.2 **Eylea 40mg/ml Solution for Injection in Vial** [Aflibercept 40mg/ml]	➢ Indication: *Visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).* *Myopic choroidal neovascularization (myopic CNV)* ➢ Posology: *Macular oedema secondary to RVO (branch RVO or central RVO)* *The recommended dose is 2mg aflibercept and is given monthly. The interval between 2 doses should not be shorter than one month.* *If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea should be discontinued.* *Monthly treatment continues until maximum visual acuity is achieved and/ or there are no signs of disease activity. Three or more consecutive, monthly injections may be needed.* *Treatment may then be continued with a treat and extend regimen with gradually increased treatment intervals to maintain stable visual and/or anatomic outcomes, however there are insufficient data to conclude on the length of these intervals. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly* *The monitoring and treatment schedule should be determined by the treating physician based on the individual patient's response.* *Monitoring for disease activity may include clinical examination, functional testing or imaging techniques (eg. Optical coherence tomography or fluorescein angiography)* *The recommended dose for Eylea is a single intravitreal injection of 2mg aflibercept (equivalent to 50 microliters solution for*	**BAYER CO. (MALAYSIA) SDN. BHD.** T1-14 Jaya 33, No.3, Jalan Semangat, Seksyen 13, 46200 Petaling Jaya, Selangor.

		injection). *Additional doses should be administered only if visual and anatomic outcomes indicate that the disease persists. Recurrences are treated like a new manifestation of the disease.* *Eylea may be dosed as frequently as once per month (4 weeks)*	
3	3.1 **STELARA 45 MG/0.5 ML SOLUTION FOR INJECTION IN PREFILLED SYRINGE** [Ustekinumab 45 mg/ 0.5 ml] 3.2 **STELARA 90 MG/1 ML SOLUTION FOR INJECTION IN PREFILLED SYRINGE** [Ustekinumab 90 mg/1 ml]	➢ Indication: *Psoriatic arthritis (PsA)* *Stelara, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.* ➢ Posology: *The recommended posology of Stelara is an initial dose of 45 mg administered subcutaneously, followed by a 45 mg dose 4 weeks later, and then every 12 weeks thereafter.* *Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg.* *Consideration should be given to discontinuing treatment in patients who have shown no response up to 28 weeks treatment.*	**JOHNSON & JOHNSON SDN BHD** Level 8, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 46150 Petaling Jaya, Selangor
4	4.1 **ALDURAZYME (LARONIDASE)** [Laronidase 2.9mg/5ml]	➢ Posology: Pediatric Use The safety and effectiveness of ALDURAZYME was assessed in a 52-week, open-label, uncontrolled clinical study in 20 patients with MPS I, ages 6 months to 5 years old, and was found to be similar to the safety and effectiveness of ALDURAZYME in pediatric patients 6 to 18 years, and adults.	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** Unit TB-18-1, Level 18, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor