PINDAAN/TAMBAHAN KEPADA FORMULARI UBAT KKM (FUKKM) BIL. 2 TAHUN 2020

BIL.	NAMA UBAT	LAMPIRAN
PENYENARAIAN UBAT BARU		
1.	*Daclatasvir 30mg & 60mg Tablet*	A1
2.	*Sofosbuvir 400mg Tablet*	
3.	*Azelastine Hydrochloride 137mcg and Fluticasone Propionate 50mcg Nasal Spray*	
4.	*Ribociclib 200mg Tablet*	
TAMBAHAN INDIKASI		
1.	*Darbepoetin Alfa 20mcg/0.5ml, 40mcg/0.5ml & 120mcg/0.5ml Injection*	A2
2.	*Human Normal Globulin Injection*	
TAMBAH KEKUATAN/ FORMULASI		
1.	*Docetaxel 20mg/ml Injection*	A3
2.	*Pregabalin 50mg Tablet*	
3.	*Timolol 0.5% Ophthalmic Gel Forming Solution*	
PINDAAN KATEGORI PRESKRIBER		
1.	*Insulin Glargine 300 units/ml Solution for Injection in Pre-Filled Pen*	A4
2.	*Indacaterol Maleate 110 mcg and Glycopyrronium Bromide 50mcg Inhalation*	
3.	*Tiotropium 2.5mcg and Olodaterol 2.5mcg Inhalation*	
4.	*Haemophilus Influenza Type B Conjugate Vaccine Injection*	
5.	*Measles and Rubella Virus Live, Attenuated Vaccine Injection*	
6.	*Diphtheria, Pertussis, Tetanus (DPT) Vaccine Injection*	
PEMANSUHAN DARIPADA FUKKM		
1.	*Diphtheria, Pertussis, Tetanus and Conjugated Haemophilus Type B 10 mcg Vaccine*	A5
2.	*Diphtheria, Pertussis, Tetanus and Hepatitis B Vaccine*	
3.	*Rubella Virus Vaccine Injection*	
4.	*Topiramate 15 mg Capsule Sprinkle*	
5.	*Vitamin K1 Mixed Micelle 2mg/0.2ml Injection*	
6.	*Sotalol HCl 160 mg Tablet*	
PENGEMASKINIAN MAKLUMAT KEPADA UBAT-UBATAN DALAM FUKKM		
1.	Pengemaskinian Maklumat Vaksin dalam FUKKM	B1
2.	Pengemaskinian Maklumat Ubat dalam FUKKM	B2

LAMPIRAN A1

UBAT-UBATAN BARU YANG DILULUSKAN UNTUK DISENARAIKAN DALAM FUKKM

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
1.	Daclatasvir 30mg & 60mg Tablet MDC: 30mg: J05AP07-110-T32-02-XXX 60mg: J05AP07-110-T32-01-XXX *Cost/unit (RM):* *30mg: RM 21.04 / tablet* *60mg: RM 2.26 / tablet* *Prescriber Category*: A/KK	*Approved Indication(s):* *To be used in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults.* *Prescribing restriction:* *None* *Dose:* *60 mg once daily, to be taken orally with or without meals.* *Dose recommendation when taking concomitant medicines:* *i. Strong inhibitors of cytochrome P450 enzyme 3A4 (CYP3A4):* *Reduce dose to 30 mg once daily when co-administered with strong inhibitors of CYP3A4.* *ii. Moderate inducers of CYP3A4:* *Increase dose to 90 mg once daily when co-administered with moderate inducers of CYP3A4.* *Daclatasvir must be administered in combination with other medicinal products for the treatment of hepatitis C infection.* *Dose modification of daclatasvir to manage adverse reactions is not recommended.* *Precaution(s):* • *Severe bradycardia and heart block - when used in combination with sofosbuvir and concomitant amiodarone with or without other drugs that lower heart rate.* • *HCV/HBV (hepatitis B virus) co-infection; retreatment with daclatasvir; interactions with medicinal products; Use in diabetic patients; patients with rare hereditary problems of galactose intolerance* • *May affect ability to drive and use machines* • *Renal impairment, hepatic impairment, elderly patients (≥ 65 years); paediatric populations; pregnancy & lactation* *Adverse reaction(s):* *i)* ***Daclatasvir in combination with sofosbuvir and ribavirin****:* *Anaemia, headache, nausea, fatigue* *ii)* ***Daclatasvir in combination with sofosbuvir:*** *Headache, fatigue*

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
		iii) ***Daclatasvir in combination with peginterferon alfa and ribavirin****:* *Fatigue, headache, pruritus, anaemia, influenza like illness, nausea, insomnia, neutropenia, asthenia, rash, decreased appetite, dry skin, alopecia, pyrexia, myalgia, irritability, cough, diarrhoea, dyspnoea and arthralgia.* *iv)* ***Other notable adverse effects when used in combination therapy:*** *Haemoglobin decreased, total bilirubin increased, severe bradycardia and heart block.* *Contraindication(s):* • *Hypersensitivity to the active substance or to any of the excipients.* • *Coadministration with medicinal products that strongly induce cytochrome P450 3A4 (CYP3A4) and P-glycoprotein transporter (P-gp) (e.g. phenytoin, carbamazepine, oxcarbazepine, phenobarbital, rifampicin, rifabutin, rifapentine, systemic dexamethasone, and the herbal product St John's wort [Hypericum perforatum]).* *Interaction(s):* *Strong CYP3A4 and P-gp inducers (e.g. phenytoin, carbamazepine, oxcarbazepine, phenobarbital, rifampicin, rifabutin, rifapentine, systemic dexamethasone, and the herbal product St John's wort), bocepravir, telaprevir, atazanavir/ritonavir, atazanavir/cobicistat, efavirenz, etravirine, nevirapine, cobicistat, clarithromycin, telithromycin, erythromycin, dabigatran etexilate, vitamin K antagonists, ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole, digoxin, amiodarone, diltiazem, nifedipine, amlodipine, verapamil, rosuvastatin and other substrates of Organic anion transporting polypeptide [OATP] 1B1 or Breast Cancer Resistance Protein [BRCP] (e.g. atorvastatin, fluvastatin, simvastatin, pitavastatin, pravastatin).* *Refer to the package insert of daclatasvir for the full list/summary of:* - *reported adverse events when used in combination with other medicinal products.* - *drug-drug interactions.*

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
2.	Sofosbuvir 400mg Tablet MDC: J05AP08-000-T32-01-XXX *Cost/unit (RM):* *RM 4.98/tablet* *Prescriber Category*: A/KK	*Approved Indication(s):* *To be used in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults.* *Prescribing restriction:* *None* *Dose:* *One 400 mg tablet, taken orally, once daily with food.* *Sofosbuvir should be used in combination with other medicinal products. Monotherapy of sofosbuvir is not recommended.* *Precaution(s):* • *Severe bradycardia and heart block - when sofosbuvir-containing regimens are used in combination with amiodarone with or without other drugs that lower heart rate.* • *HCV/HBV co-infection; treatment-experienced patients with genotype 1 and 4 HCV infection; patients with genotype 5 or 6 HCV infection; interferon-free therapy for genotype 1 HCV infection; co-administration with other direct-acting antivirals against HCV; use with moderate P-gp inducers; use in diabetic patients* • *May affect ability to drive and use machines* • *Renal impairment; hepatic impairment; elderly patients (≥ 65 years); paediatric populations; pregnancy & lactation* *Adverse reaction(s):* ***i. Sofosbuvir in combination with ribavirin*** *Haemoglobin decreased, insomnia, headache, nausea, blood bilirubin increased, fatigue, irritability.* ***ii. Sofosbuvir in combination with peginterferon alfa and ribavirin:*** *Anaemia, neutropenia, lymphocyte count decreased, platelet count decreased, decreased appetite, insomnia, dizziness, headache, dyspnoea, cough, diarrhoea, nausea, vomiting, blood bilirubin increased, rash, pruritus, arthralgia, myalgia, chills, fatigue, influenza-like illness, irritability, pain, pyrexia.* ***iii. Other notable adverse effects when used in combination therapy:*** • *Cases of severe bradycardia and heart block have been observed when sofosbuvir containing-regimes are used in*

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
		combination with amiodarone and/or other medicinal products that lower heart rate. • *Steven-Johnson syndrome.* • *Elevated total bilirubin (grade 3 or 4) in HCV/HIV co-infected patients receiving atazanavir as part of the antiretroviral regimen.* • *Pancytopenia (particularly in subjects receiving concomitant pegylated interferon).* • *Severe depression (particularly in patients with pre-existing history of psychiatric illness), including suicidal ideation and suicide.* *<u>Contraindication(s):</u>* • *Hypersensitivity to the active substance or to any of the excipients.* • *Co-administration with medicinal products that are strong P-gp inducers in the intestine (e.g. carbamazepine, phenobarbital, phenytoin, rifampicin and St. John's wort).* *<u>Interaction(s):</u>* *Strong P-gp inducers in the intestine (e.g. carbamazepine, phenobarbital, phenytoin, rifampicin and St.John's wort), moderate P-gp inducers in the intestine (e.g. modafinil, oxcarbazepine and rifapentine), amiodarone, vitamin K antagonist, drugs metabolized by liver such as immunosuppressants (e.g. ciclosporin, tacrolimus).* *Refer to package insert of sofosbuvir for the full list/summary of:* - *reported adverse events when used in combination with ribavirin, with or without peginterferon-alfa* - *drug-drug interactions*
3.	Azelastine Hydrochloride 137mcg and Fluticasone Propionate 50mcg Nasal Spray <u>MDC:</u> R01AD58-984-A41-01-XXX *<u>Cost/unit (RM):</u>* *RM33.00 /bottle* *<u>Prescriber Category</u>*: A*	*<u>Approved Indication(s):</u>* *Symptomatic treatment of moderate to severe allergic rhinitis and rhino-conjunctivitis in adults and children 12 years and older where use of a combination (intranasal antihistamine and glucocorticoid) is appropriate* *<u>Prescribing restriction:</u>* *As a second line treatment: only for those whose symptoms remain uncontrolled on oral antihistamine or intranasal corticosteroids (INS) monotherapy, or on a combination of oral antihistamine plus INS.* *<u>Dose:</u>* *One actuation in each nostril twice daily*

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
		Precaution(s): *Somnolence, local effects e.g., nasal ulceration and nasal septal perforation, glaucoma and cataracts, hypothalamic-pituitary-adrenal axis effects, effect on children growth rate.* *Not recommended for use in patients below 12 years old.* *Adverse reaction(s):* *Headache, dysgeusia, unpleasant smell, epistaxis, nasal discomfort, sneezing, nasal dryness, cough, dry throat, throat irritation, nervousness, taste loss, dry mouth* *Contraindication(s):* *Hypersensitivity to the active substance(s) or to any of the excipients* *Interaction(s):* *Central nervous system depressants, cytochrome P450 inhibitors*
4.	Ribociclib 200mg Tablet MDC: L01XE42-105-T32-01-XXX *Cost/unit (RM):* *RM 47.59/ tablet* *Prescriber Category*: *A* (Oncologist only)*	*Approved Indication(s):* *In combination with:* • *an aromatase inhibitor for the treatment of postmenopausal women, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy.* *Prescribing restriction:* *Not applicable* *Dose:* *600 mg daily for 21 consecutive days followed by 7 days off treatment. Can be taken with or without food. For dose modification, refer package insert.* *Precaution(s):* *QT interval prolongation, increased QT prolongation with concomitant use of CYP3A4 substrates and tamoxifen, hepatobiliary toxicity, neutropenia and embryo-foetal toxicity.* *Adverse reaction(s):* *Neutropenia, nausea, fatigue, diarrhoea, leukopenia, alopecia, vomiting, constipation, headache, back pain, abnormal liver function tests, lymphopenia and vomiting.*

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
		<u>Contraindication(s):</u> *Hypersensitivity to the active substance or to peanut, soya or any of the excipients.* *<u>Interaction(s):</u>* *CYP3A4 inhibitors & inducers, sensitive CYP3A substrate with narrow therapeutic index and medicinal products with a known potential to prolong QT such as antiarrhythmic medicines.*

LAMPIRAN A2

TAMBAHAN INDIKASI YANG DILULUSKAN BAGI UBAT-UBATAN YANG TERSENARAI DALAM FUKKM

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
1.	*Darbepoetin Alfa 20mcg/0.5ml, 40mcg/0.5ml & 120mcg/0.5ml Injection* *Cost/unit (RM):* *20mcg/0.5ml: RM45/syringe* *40mcg/0.5ml:* *RM 86.00/syringe* *120mcg/0.5ml:* *RM250.00/syringe* *Prescriber Category: A**	*Approved to add indication(s):* *Anemia with myelodysplastic syndrome* *Prescribing Restriction: -* *None*	*Dose:* *Adults: 240mcg administered as a single subcutaneous injection once weekly. The dose should be decreased in view of the degree of anemic symptoms and the patient's age.* *Refer MOHMF for other information.*
2.	*Human Normal Globulin (IVIG) Injection* *Cost/unit (RM):* ***IVIG 3g*** *(*supplied by Pusat Darah Negara)* ***IVIG 2.5g*** ***(APPL item):*** *Peninsular Malaysia:* *RM 487.20 / vial* *Sabah & Sarawak:* *RM 491.40 / vial* *Prescriber Category: A*	*Approved to add indication(s):* *Guillain-Barré Syndrome (GBS).* *Prescribing Restriction: -* *None*	*Dose:* *Adult dose: 0.4 gm/kg/day for 5 days via intravenous infusion* *Refer MOHMF for other information.*

LAMPIRAN A3

TAMBAHAN FORMULASI/KEKUATAN YANG DILULUSKAN BAGI UBAT-UBATAN YANG TERSENARAI DALAM FUKKM.

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
1.	*Docetaxel 20mg/ml Injection*	*Approved to add new formulation:* *Docetaxel 20mg/ml Injection* MDC: L01CD02-000-P30-03-XXX *Cost/unit (RM):* *RM63.90/vial* *Prescriber Category*: *A**	*Approved Indication(s):* *For solid tumours such as: breast cancer; non-small cell lung cancer; prostate cancer; gastric adenocarcinoma; head and neck cancer; ovarian cancer.* *Prescribing restriction:* *Not applicable* *Dose:* *i. 50 mg/m^2 every 2 weeks, intravenous* *ii. 75 to 100 mg/m^2 every 3 weeks, intravenous.* *Dosing is according to Product Insert.* *Precaution(s):* *Premedication with corticosteroids against fluid retention/hypersensitivity reactions. Neutropenia, gastrointestinal reactions, hypersensitivity reactions, cutaneous reactions, fluid retention, respiratory disorders, patients with liver & renal impairment, peripheral neurotoxicity, cardiac toxicity & eye disorders. Pregnancy & Lactation.* *Adverse reaction(s):* *Neutropenia, anaemia, alopecia, nausea, vomiting, stomatitis, diarrhoea & asthenia. Severity of adverse events may increase when given in combination with other chemotherapeutic agents.* *Contraindication(s):* *Hypersensitivity to the active substance or to any of the excipients, baseline neutrophil count of <1,500 cells/mm^3, severe liver impairment.*

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
			Interaction(s): *CYP3A4 inducers, inhibitors, or substrates may alter docetaxel metabolism. When combined to docetaxel, clearance of carboplatin is 50% higher than in monotherapy.*
2.	Pregabalin 75 mg Capsule Pregabalin 150 mg Capsule	*Approved to add new formulation:* *Pregabalin 50 mg Capsule* MDC: N03AX16-000-C10-03-XXX *Cost/unit (RM):* *Market Price* *Prescriber Category*: *A**	*Approved Indication(s):* *i) Neuropathic pain* *ii) Fibromyalgia* *iii) Epilepsy* *Prescribing Restriction(s):* *Not applicable* *Dose:* *The dose range is 150 to 600 mg per day given in either two or three divided doses. Dosing is according to Product Insert.*
3.	Timolol Maleate 0.5% Eye Drops	*Approved to add new formulation:* *Timolol 0.5% Ophthalmic Gel Forming Solution* MDC: S01ED01-253-D20-02-XXX *Cost/unit (RM):* *RM 18.44 per bottle of 2.5mL via Central Contract* *Prescriber Category*: *A*	*Approved Indication(s):* *Elevated intraocular pressure, chronic open angle glaucoma* *Prescribing Restriction(s):* *Not applicable* *Dose:* *One drop in the affected eye(s)* ***once a day***

LAMPIRAN A4

PINDAAN KATEGORI PRESKRIBER YANG DILULUSKAN BAGI UBAT-UBATAN YANG TERSENARAI DALAM FUKKM

BIL	NAMA GENERIK	KETERANGAN PINDAAN
1.	*Insulin Glargine 300 units/ml Solution for Injection in Pre-Filled Pen*	*Change in the prescriber category from A* to A/KK* *<u>Cost/unit (RM):</u>* *RM49.80/prefilled pen* *<u>Prescribing restriction:</u>* *For usage in Primary Care Facilities:* *1. Can be prescribed only by Family Medicine Specialist.* *2. Patient must meet all the following criteria:* *i. Patient on high dose insulin >30units per injection;* *ii. Patient with BMI >35kg/m^2; and* *iii. Patient who develops significant hypoglycaemia with Insulin Glargine 100units/ml or Insulin Determir 100units/ml after ruling out other causes of hypoglycaemia.* *Note: Used for a trial of 3 months, if during this period patients still develop similar episodes of hypoglycaemia, revert back to human insulins or refer patients to endocrinologist.*
2.	*Indacaterol Maleate 110 mcg and Glycopyrronium Bromide 50mcg Inhalation*	*Change in the prescriber category from A* to A/KK* *<u>Cost/unit (RM):</u>* *RM82.40 /30 capsules* *<u>Prescribing restriction in Primary Care Facilities:</u>* *Patients **with** inhaler coordination problem*
3.	*Tiotropium 2.5mcg and Olodaterol 2.5mcg inhalation*	*Change in the prescriber category from A* to A/KK* *<u>Cost/unit (RM):</u>* *RM82.00 /unit* *<u>Prescribing restriction in Primary Care Facilities:</u>* *Patients **without** inhaler coordination problem*

BIL	NAMA GENERIK	KETERANGAN PINDAAN
4.	*Haemophilus Influenza Type B Conjugate Vaccine Injection*	*Change in the prescriber category from C to C+* *<u>Cost/unit (RM):</u>* *41.53 (West Malaysia) / 41.89 (East Malaysia) via APPL* *<u>Justification:</u>* *Vaccine is listed in the National Immunisation Programme.*
5.	*Measles and Rubella Virus Vaccine Live, Attenuated Vaccine Injection*	*Change in the prescriber category from C to C+* *<u>Cost/unit (RM):</u>* *87.00/vial of 10 doses via Central Contract* *<u>Justification:</u>* *Vaccine is listed in the National Immunisation Programme.*
6.	*Diphtheria, Pertussis, Tetanus (DPT) Vaccine Injection*	*Change in the prescriber category from C to C+* *<u>Cost/unit (RM):</u>* *Market Price* *<u>Justification:</u>* *Vaccine is listed in the National Immunisation Programme.*

Nota:
A (Consultant/ Specialists from disciplines related to the listed indication only)*
A (Consultant/Specialists)
A/KK (Consultant/ Specialists/ Family Medicine Specialists)
B (Medical Officer)
C (Paramedics)
C+ (Paramedics doing midwifery)

LAMPIRAN A5

UBAT-UBATAN YANG DIMANSUHKAN DARIPADA FUKKM

BIL	NAMA GENERIK	JUSTIFIKASI PEMANSUHAN	ALTERNATIF DALAM FUKKM
1.	Diphtheria, Pertussis, Tetanus and Conjugated Haemophilus Type B 10 mcg Vaccine	1. Tiada produk berdaftar di Malaysia. 2. Tiada penggunaan sejak tahun 2018. *3.* Terdapat alternatif dalam FUKKM (produk vaksin kombinasi)	**Kombinasi:** 1. Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio Virus, Haemophilus Influenza Type B (DTaP-IPV-HiB) Vaccine Injection 2. Hepatitis B Vaccine Injection
2.	Diphtheria, Pertussis, Tetanus and Hepatitis B Vaccine		
3.	Rubella Virus Vaccine Injection	1. Tiada penggunaan sejak tahun 2018. 2. Terdapat alternatif dalam FUKKM (produk vaksin kombinasi)	Measles, Mumps and Rubella (MMR) Vaccine Injection
4.	Topiramate 15 mg Capsule Sprinkle	1. Penarikan balik produk daripada pasaran Malaysia oleh pemegang pendaftaran produk 2. Terdapat alternatif dalam FUKKM	1. Topiramate 25mg Capsule Sprinkle 2. Topiramate 25mg / 50mg / 100mg Tablet
5.	Vitamin K1 Mixed Micelle 2mg/0.2ml Injection	1. Tiada produk berdaftar di Malaysia 2. Tiada penggunaan sejak 2019 3. Terdapat alternatif dalam FUKKM	1. Vitamin K1 1 mg/ml Injection
6.	Sotalol HCl 160 mg Tablet	1. Tiada penggunaan sejak tahun 2017 2. Tiada produk berdaftar di Malaysia 3. Terdapat alternatif dalam FUKKM	1. Verapamil 40mg Tablet 2. Sotalol HCL 80mg Tablet

PENGEMASKINIAN MAKLUMAT VAKSIN DALAM FUKKM (NAMA GENERIK, INDIKASI & DOS)

NO.	NAMA GENERIK/ KATEGORI PREKRIBER / KAEDAH PEROLEHAN	INDIKASI FUKKM	DOS FUKKM	PENGEMASKINIAN			JUSTIFIKASI PINDAAN
				NAMA GENERIK	INDIKASI	DOS	
1.	Diphtheria, Pertussis, Tetanus Vaccine Injection **Kategori Preskriber:** C+ **Kaedah Perolehan:** LP	*Prophylactic immunisation against diphtheria, pertussis and tetanus*	By deep SC or IM injection: 3 doses each of 0.5 or 1 ml with intervals of 6 - 8 weeks and 4 - 6 months respectively between the doses. Booster 1 and 5 years after primary immunisation.	[redacted]	*Immunisation against diphtheria, pertussis and tetanus.*	0.5ml by IM. **Dosing is according to Immunisation Schedule under NIP.**	Pengemaskinian maklumat indikasi dan dos berdasarkan NIP.
2.	Diphtheria and Tetanus Vaccine Injection **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL	*Immunisation against diphtheria and tetanus.*	Prophylactic: 2 or 3 doses by deep SC or IM injection, 0.5 or 1 ml. Each second dose at 4 - 6 weeks then 4 - 6 months. Booster at 4 - 6 years.			0.5ml by deep SC or IM injection. **Dosing is according to Immunisation Schedule under NIP.**	Pengemaskinian dos berdasarkan NIP.
3.	Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio Virus, Haemophilus Influenza Type B (DTaP-IPV-HiB) Vaccine Injection **(Single Dose)** **Kategori Preskriber:** C+ **Kaedah Perolehan:** Kontrak Pusat	*Immunisation of children against Diphtheria, Tetanus, Acellular Pertussis, Polio and Haemophilus Influenza Type B infection*	Primary: 0.5 ml by IM at 1 - 2 months intervals Booster: Second year of life.	Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio Virus, Haemophilus Influenza Type B (DTaP-IPV-HiB) Vaccine Injection		0.5ml by IM. **Dosing is according to Immunisation Schedule under NIP.**	Pengemaskinian nama generik berdasarkan produk berdaftar dan maklumat dos berdasarkan NIP.

NO.	NAMA GENERIK/ KATEGORI PREKRIBER / KAEDAH PEROLEHAN	INDIKASI FUKKM	DOS FUKKM	PENGEMASKINIAN			JUSTIFIKASI PINDAAN
				NAMA GENERIK	INDIKASI	DOS	
4.	Meningococcal A, C, Y, W 135 Vaccine Injection **Kategori Preskriber:** B **Kaedah Perolehan:** APPL	*Immunisation against meningococcal diseases caused by Neisseria meningitis Group A, Group C, Group Y or Group W-135.*	Prophylaxis: 0.5 ml intramuscular injection.	Meningococcal **Group** A, C, Y, W-135 Vaccine Injection	[redacted]	0.5ml by IM.	Pengemaskinian nama generik dan maklumat dos berdasarkan produk berdaftar.
5.	Poliomyelitis Oral Live Vaccine **(10 Doses)** **Kategori Preskriber:** C+ **Kaedah Perolehan:** LP	*Immunisation against poliomyelitis.*	Two drops (0.1 ml). Primary immunization: 1 oral dose at 3,4 & 5 month of age. Booster doses at 1-4 years & 7 years.	Poliomyelitis Oral Live Vaccine		0.1ml (two drops) by oral. **Dosing is according to local and WHO recommendations.**	Pengemaskinian nama generik berdasarkan maklumat produk berdaftar. Pengemaskinian maklumat dos berdasarkan cadangan daripada Bahagian Kawalan Penyakit dan WHO. Vaksin ini digunakan sebagai *Supplementary Immunisation Activities* (SIA) sebagai respons kepada wabak polio.
6.	Rabies Vaccine Injection **Kategori Preskriber:** B **Kaedah Perolehan:** Kontrak Pusat	*Pre-exposure and post-exposure vaccination against rabies.*	**Pre-exposure (prophylaxis):** 3 doses scheduled on D0, D7 and D28. Booster dose after every 6 months to 5 years (refer to manufacturer's recommendations). **Post-exposure prophylaxis:** use after attack of a potential rabid animal: 1 dose on D0, D3, D7, D14 and D28. In previously vaccinated individuals 2 doses on D0 and D3.	[redacted]		1ml by IM. **Dosing is according to product insert based on patient's needs (pre and post exposure).**	Pengemaskinian maklumat dos berdasarkan maklumat produk berdaftar dan keperluan pesakit *(pre and post exposure).*

NO.	NAMA GENERIK/ KATEGORI PREKRIBER / KAEDAH PEROLEHAN	INDIKASI FUKKM	DOS FUKKM	PENGEMASKINIAN			JUSTIFIKASI PINDAAN
				NAMA GENERIK	INDIKASI	DOS	
7.	BCG Vaccine Freeze-Dried Injection **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL	*For the prevention of tuberculosis.*	0.1 ml by intradermal injection. INFANT under 12 months: 0.05 ml.			0.05 to 0.1 ml by intradermal. **Dosing is according to Immunisation Schedule under NIP.**	Pengemaskinian maklumat dos berdasarkan NIP dan
8.	Typhoid Vaccine Injection **(20 doses)** **Kategori Preskriber:** B **Kaedah Perolehan:** APPL	*Active immunization against typhoid fever in adult and child more than 2 years.*	0.5 ml single IM injection into the deltoid or vastus lateralis, may reimmunize with 0.5 ml IM every 3 years if needed.	Typhoid Vaccine Injection			Pengemaskinian nama generik berdasarkan produk berdaftar di pasaran.
9.	Cholera Vaccine Injection **Kategori Preskriber:** B **Kaedah Perolehan:** LP	*Immunisation of cholera.*	Prophylactic ADULT: First dose of 0.5 ml SC/IM followed after 1 - 4 weeks by a second dose of 1 ml. CHILD: 1 - 5 years: 0.1 ml (1st dose), 0.3 ml (2nd dose). CHILD; 5 - 10 years: 0.3 ml (1st dose), 0.5ml (2nd dose). Booster: For optimum long-term protection, a booster dose is recommended for adults after 2 years. Children 2-6 years should receive a booster dose after 6 months.	Cholera Vaccine **Oral Suspension**	Immunisation against cholera.	Two doses of vaccines should be given at an interval of two weeks.	Pengemaskinian nama generik, maklumat indikasi dan dos berdasarkan semakan dengan maklumat produk berdaftar yang terkini **(hanya terdapat dalam bentuk dosej oral sahaja).**
10.	Measles Vaccine Injection **(10 doses)** **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL	*Prophylaxis against measles and to prevent development of infection (if given within 72 hours of contact).*	By SC or IM injection, 0.5 ml as a single dose at 12 - 15 months of age.	Measles Vaccine Injection	Immunisation against measles.	0.5ml by SC or IM. **Dosing is according to Immunisation Schedule under NIP.**	Pengemaskinian nama generik berdasarkan produk berdaftar serta maklumat indikasi dan dos berdasarkan NIP.

NO.	NAMA GENERIK/ KATEGORI PREKRIBER / KAEDAH PEROLEHAN	INDIKASI FUKKM	DOS FUKKM	PENGEMASKINIAN			JUSTIFIKASI PINDAAN
				NAMA GENERIK	INDIKASI	DOS	
11.	Measles and Rubella Virus Vaccine Live, Attenuated **(Freeze-dried) 10 doses/vial** **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL	*For active immunization against measles and rubella in infants, children, adolescents and young adults at risk. Immunization of susceptible non-pregnant adolescent and adult females is indicated if certain precautions are observed. The vaccine can be safely and effectively given simultaneously with DTP, DT, TT, Td, BCG, Polio Vaccine (OPV and IPV), Haemophilus influenza type B, Hepatitis B, Yellow fever vaccine and vitamin A supplementation.*	The vaccine should be reconstituted only with the diluent supplied (sterile water for injection) using a sterile syringe and needle. With gentle shaking the dried cake is easily dissolved. After reconstitution the vaccines should be used immediately. A single dose of 0.5ml should be administered by deep SC injection into the anterolateral aspect of upper thigh in infants and upper arm in older children. If the vaccines is not used immediately then it should be stored in the dark at 20°C and 80°C for no longer than 6 hours.	Measles and Rubella Virus Live, Attenuated Vaccine Injection	Immunisation against measles and rubella.	0.5ml by deep SC injection. **Dosing is according to Immunisation Schedule under NIP and product insert.**	Pengemaskinian nama generik dan maklumat indikasi serta dos berdasarkan NIP.
12.	Measles, Mumps and Rubella (MMR) Vaccine Injection **(Single Dose)** **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL	*For immunisation of children against measles, mumps and rubella.*	Subcutaneous or by intramuscular injection, 0.5 ml.	Measles, Mumps and Rubella (MMR) Vaccine Injection		0.5ml by SC or IM. **Dosing is according to Immunisation Schedule under NIP.**	Pengemaskinian nama generik berdasarkan produk berdaftar dan maklumat dos berdasarkan NIP.
13.	Hepatitis A **Inactivated** Vaccine **Kategori Preskriber:** A **Kaedah Perolehan:** LP	*Vaccination against hepatitis A especially in those at risk of exposure to hepatitis A virus such as:* *i. Visitors* *ii. Chronic hepatitis B and C patient* *iii. Those requiring vaccination against hepatitis A*	0.5 ml per injection. ADULT and CHILD more than 15 years: A single primary dose followed by a booster dose 6 - 12 months later. CHILD 2 - 15 years: A single primary dose followed by a booster dose 6 - 12 months later.	Hepatitis A Vaccine Injection	Immunisation against Hepatitis A.	0.5 – 1.0 ml by IM. **Dosing is according to product insert.**	Pengemaskinian nama generik, maklumat indikasi dan dos berdasarkan semakan dengan produk berdaftar.

NO.	NAMA GENERIK/ KATEGORI PREKRIBER / KAEDAH PEROLEHAN	INDIKASI FUKKM	DOS FUKKM	PENGEMASKINIAN			JUSTIFIKASI PINDAAN
				NAMA GENERIK	INDIKASI	DOS	
14.	Hepatitis B Vaccine Injection **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL	*Immunisation against infections caused by Hepatitis B virus.*	Dose depends on the products used. Please refer to package insert. Example: 1. Euvax-B Adult (from 16 years old) - 20mcg/dose Neonates, infants & children up to and including 15 years - 10mcg/dose. 2. Engerix-B Adult (from 20 years old) - 20mcg/dose Neonates, infants & children up to and including 19 years - 10mcg/dose. Second dose to be given after 1 month and booster dose after 6 months.			0.5 – 1.0 ml by IM. **Dosing is according to Immunisation Schedule under NIP and product insert.**	Pengemaskinian maklumat dos berdasarkan NIP dan maklumat produk berdaftar.
15.	Haemophilus Influenza Type B Conjugate Vaccine Injection **(Single Dose)** **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL	*Immunisation of infants against Haemophilus Influenzae Type B*	0.5 ml IM.	Haemophilus Influenza Type B Conjugate Vaccine Injection		0.5ml by IM. In patients with thrombocytopenia or bleeding disorders, vaccine can be administered by SC.	Pengemaskinian nama generik dan maklumat dos berdasarkan semakan dengan produk berdaftar.
16.	Influenza Vaccine (Inactivated) Injection **Kategori Preskriber:** B **Kaedah Perolehan:** LP	*i) Prophylaxis of influenza for frontliners (KKM staff and essential services personnel).* *ii) Prophylaxis of influenza in high risk groups, particularly* ***individuals who have chronic cardiovascular, pulmonary, metabolic or renal disease, or who are immunocompromised and elderly patients.*** *Refer to current recommendation by WHO for selection of product of inactivated influenza vaccines.*	CHILD 6-35 months: Single dose of 0.5 ml IM or deep SC; 3-8 years: 1-2 doses of 0.5 ml IM ADULT & CHILD more than 9 years: Single dose of 0.5 ml IM		i) Prophylaxis of influenza for frontliners (KKM staff and essential services personnel). ii) Prophylaxis of influenza in high risk groups. Refer to current recommendation by WHO for selection of product of inactivated influenza vaccines.	0.25ml to 1.0ml by IM. **Dosing is according to product insert and WHO recommendations.**	Pengemaskinian maklumat indikasi dan dos berdasarkan semakan dengan produk berdaftar.

NO.	NAMA GENERIK/ KATEGORI PREKRIBER / KAEDAH PEROLEHAN	INDIKASI FUKKM	DOS FUKKM	PENGEMASKINIAN			JUSTIFIKASI PINDAAN
				NAMA GENERIK	INDIKASI	DOS	
17.	Human Papillomavirus (Types 16, 18) Vaccine Injection **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL	*For the prevention of cervical cancer due to papilloma virus. To be used as part of the **public health program** only.*	Given by IM into deltoid region or higher anterolateral thigh. ADULT and CHILD 9 - 26 years, 3 doses of 0.5 mL, at 0, 2 and 6 months		For the prevention of cervical cancer due to papilloma virus. Prescribing restriction: To be used as part of **NIP** only.		Pengemaskinian berdasarkan maklumat vaksin dalam NIP.
18.	Human Papillomavirus (Types 6, 11, 16, 18) Vaccine Injection **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL						
19.	Varicella Virus Vaccine Live Attenuated Injection **Kategori Preskriber:** A* **Kaedah Perolehan:** LP	*i. Health staff working with children, pregnant women, transplant, cancer and immunocompromised patients who are at high risk of contracting varicella and transmitting it to at risk patients* *ii. Transplant patients or candidates who are:* *a) Immunocompetent and not receiving immunosuppressant drugs, do not have graft versus host disease 2 years or more after transplant* *b) Susceptible to Varicella-Zoster virus at least 3 weeks before grafting* *iii. Children:* *a) with impaired humoral immunity* *b) HIV-infected children more than 12 months of age, in CDC class N1 (asymptomatic) or A1 (mildly symptomatic) with age specific CD4 more than 25%*	ADULT and CHILD 13 years or more: 2 doses of 0.5 ml SC injection separated by 4 - 8 weeks apart. CHILD 12 months - 12 years: 2 doses at least 3 months apart. However, if the second dose is administered a minimum of 28 days after the first dose, it does not need to be repeated.		Immunisation against varicella virus infection.	0.5ml by SC. **Dosing is according to product insert.**	Pengemaskinian maklumat indikasi dan dos berdasarkan semakan dengan produk berdaftar.

NO.	NAMA GENERIK/ KATEGORI PREKRIBER / KAEDAH PEROLEHAN	INDIKASI FUKKM	DOS FUKKM	PENGEMASKINIAN			JUSTIFIKASI PINDAAN
				NAMA GENERIK	INDIKASI	DOS	
		c) with conditions that require systemic steroid therapy less than 2 mg/kg body weight or a total of 20 mg/day of prednisolone or its equivalent. [Those receiving high doses of systemic steroids at 2 mg/kg body weight or more of prednisolone for more than 2 weeks may be vaccinated after steroid therapy has been discontinued for at least three months] *iv. Acute lymphoblastic leukaemia (ALL) patients with negative history of varicella who:* *a) are 12 months to 17 years of age* *b) have leukaemia in remission for at least 12 months* *c) have a peripheral blood lymphocyte count 700 cells/ mm3 or more. [If platelet count of greater 100,000/mm3 within 24 hours of vaccination are not being submitted to radiotherapy. Chemotherapy should be withheld for seven days before and after immunisation]* *v. Susceptible subjects in clinical trials who will be submitted for chemotherapy* *vi. Children and susceptible patients on chronic dialysis*					

NO.	NAMA GENERIK/ KATEGORI PREKRIBER / KAEDAH PEROLEHAN	INDIKASI FUKKM	DOS FUKKM	PENGEMASKINIAN			JUSTIFIKASI PINDAAN
				NAMA GENERIK	INDIKASI	DOS	
20.	Tetanus Toxoid Injection **Kategori Preskriber:** C+ **Kaedah Perolehan:** APPL	*Immunisation against tetanus infection.*	2 doses of 0.5 mL IM at an interval of 4-8 weeks, followed by the 3rd dose 6-12 months later. Booster: 0.5 mL IM every 10 years.			0.5 mL by IM. **Dosing is according to product insert.**	Pengemaskinian maklumat dos berdasarkan semakan produk berdaftar.

Nota:
LP: *Local Purchase* (Pembelian Tempatan), **APPL**: *Approved Products Purchase List*

PENGEMASKINIAN MAKLUMAT UBAT DALAM FUKKM

1. PENGEMASKINIAN MAKLUMAT *PRESCRIBING RESTRICTIONS*

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / *PRESCRIBING RESTRICTIONS*		JUSTIFIKASI /TINDAKAN
		ASAL	BARU	
1.0 NERVOUS SYSTEM				
1.	Oxycodone Hydrochloride 10mg Controlled Release Tablet (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	*Management of moderate to severe chronic cancer pain non-responsive to morphine in accordance with WHO step-wise ladder of chronic pain management.* ***Initiated by:*** ***i) palliative medicine physicians*** ***ii) oncologists*** ***iii) anaesthesiologists*** ***iv) haematologists and*** ***v) pain specialists only***	*Management of moderate to severe chronic cancer pain non-responsive to morphine in accordance with WHO step-wise ladder of chronic pain management.*	***Removed*** *Prescribing Restrictions* - *To* ***allow Specialists other than Chronic Pain Specialists*** *treating cancer patients to prescribe* - *To harmonise for Pain Free Programme – as outlined in* ***Pain as 5th Vital Sign Guidelines (3rd ed.)***
2.	Oxycodone Hydrochloride 20mg Controlled Release Tablet (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP			
3.	Oxycodone Hydrochloride 40mg Controlled Release Tablet (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP			
4.	Oxycodone Hydrochloride 5 mg and Naloxone Hydrochloride Dihydrate 2.5mg Tablet (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	The management of moderate to severe chronic pain unresponsive to non-narcotic analgesics. The opioid antagonist naloxone in the fixed combination is added to counteract and/or prevent opioid-induced constipation. **For pain specialist only**	The management of moderate to severe chronic pain unresponsive to non-narcotic analgesics. The opioid antagonist naloxone in the fixed combination is added to counteract and/or prevent opioid-induced constipation.	***Removed*** *Prescribing Restrictions* - *To* ***allow Specialists other than Chronic Pain Specialists*** *treating cancer patients to prescribe* - *To harmonise for Pain Free Programme – as outlined in* ***Pain as 5th Vital Sign Guidelines (3rd ed.)***

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / *PRESCRIBING RESTRICTIONS*		JUSTIFIKASI /TINDAKAN
		ASAL	BARU	
5.	Oxycodone Hydrochloride 10mg and Naloxone Hydrochloride Dihydrate 5mg Tablet (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP			
6.	Oxycodone Hydrochloride 20mg and Naloxone Hydrochloride Dihydrate 10mg Tablet (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP			
7.	Oxycodone Hydrochloride 40mg and Naloxone Hydrochloride Dihydrate 20mg Tablet (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP			
8.	Oxycodone HCl 5 mg Immediate Release Capsules (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	i) As a **second line drug** in the management of opioid responsive, moderate to severe chronic cancer pain ii) As a step-down analgesic drug in post-operative procedures **Initiated by:** **i) palliative medicine physicians** **ii) oncologists** **iii) anaesthesiologists** **iv) haematologists and** **v) pain specialists only**	*i) Management of **moderate to severe chronic cancer pain non-responsive to morphine** in accordance with **WHO step-wise ladder** of chronic pain management* *ii) As a step-down analgesic drug in post-operative procedures*	**1. *Removed*** *Prescribing Restrictions* - *To **allow Specialists other than Chronic Pain Specialists** treating cancer patients to prescribe* - *To harmonise for Pain Free Programme – as outlined in **Pain as 5th Vital Sign Guidelines (3rd ed.)*** **2. *Amended*** *indication (i) based on expert opinion*
9.	Oxycodone HCl 10 mg Immediate Release Capsules (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A*			

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / *PRESCRIBING RESTRICTIONS*		JUSTIFIKASI /TINDAKAN
		ASAL	BARU	
	Kaedah Perolehan: LP			
10.	Oxycodone HCl 20 mg Immediate Release Capsules (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	***Note:*** ***DCA Indication*** *The management of opioid responsive, moderate to severe pain*		
11.	Fentanyl 50 mcg/h Transdermal Patch (3 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat	As a second line drug in the management of chronic cancer pain. **The use is to be restricted to:** **i) pain specialists;** **ii) palliative medicine specialists; and** **iii) oncologists** ***Note: DCA Indications*** *Management of **chronic pain** and **intractable pain** that requires continuous **opioid** administration for an extended period of time.*	*As a second line drug in the management of **opioid responsive, moderate to severe chronic cancer pain*** **PRECAUTIONS:** **Not to be used in opioid naive patients.**	***1.*** *Removed Prescribing Restrictions* - *To **allow Specialists other than Chronic Pain Specialists** treating cancer patients to prescribe* - *To harmonise for Pain Free Programme – as outlined in **Pain as 5th Vital Sign Guidelines (3rd ed.)*** ***2. Amended** indication and **added** Precautions based on expert opinion*
12.	Fentanyl 25 mcg/h Transdermal Patch (3 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat			
13.	Fentanyl 12mcg/h Transdermal Patch (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	As a second line drug in the management of chronic severe cancer pain **not responding to non-narcotic analgesic**. **Not to be used in opioid naive patients.** **The use is to be restricted to:** **i) pain specialists;** **ii) palliative medicine specialists; and** **iii) oncologists**	*As a second line drug in the management of **opioid responsive, moderate to severe chronic cancer pain*** **PRECAUTIONS:** **Not to be used in opioid naive patients.**	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / *PRESCRIBING RESTRICTIONS*		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
2.0 RESPIRATORY SYSTEM				
1.	Glycopyrronium 50mcg, Inhalation Powder Hard Capsules (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A/KK **Kaedah Perolehan:** LP	**PRESCRIBING RESTRICTION** Nil	i) The diagnosis of COPD should be confirmed by spirometry	***Streamlined** Prescribing Restrictions for Glycopyrronium, Indacaterol and Tiotropium*

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / *PRESCRIBING RESTRICTIONS*		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
2.	Indacaterol Maleate 150 mcg Inhalation Capsule (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A/KK **Kaedah Perolehan:** LP	**PRESCRIBING RESTRICTION** Initiation of LABA, LAMA and LABA/LAMA for COPD: **i) The diagnosis of COPD should be confirmed by spirometry** **ii) For Pulmonologist: COPD patient must be assessed for suitability for lung volume reduction (surgical or bronchoscopic approach) and lung transplant before they are discharged to Klinik Kesihatan.** **iii) For Family Medicines Specialist: COPD patients must be referred to Pulmonologist for assessment of suitability for lung volume reduction (surgical or bronchoscopic approach) and lung transplant prior initiation of LABA, LAMA and LABA/LAMA in Klinik Kesihatan.**		
3.	Tiotropium 2.5mcg/puff solution for inhalation (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A/KK **Kaedah Perolehan:** Kontrak Pusat	**PRESCRIBING RESTRICTION** Nil		

PENGEMASKINIAN MAKLUMAT UBAT DALAM FUKKM

2. PENGEMASKINIAN MAKLUMAT INDIKASI DAN DOS

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
1.0 Anti-Infectives for Systemic Use				
1.	Acyclovir 250 mg Injection (5 produk berdaftar/ *Multisource*) **Kategori Preskriber**: A* **Kaedah Perolehan**: APPL	**INDICATION** **Treatment and prophylaxis of herpes simplex in immunocompromised, severe initial genital herpes and Varicella -Zoster**	**INDICATION** i)Treatment of Herpes simplex & Varicella zoster infections ii)Prophylaxis of Herpes simplex infections in immune-compromised patients	***Streamlined*** *indications for Acyclovir tablets and injection based on* ***registered DCA indications***
2.	Acyclovir 200mg Tablet (10 produk berdaftar/ *Multisource*) **Kategori Preskriber**: A/KK **Kaedah Perolehan**: APPL	**INDICATION** **i) Mucocutaneous Herpes Simplex infection in immunocompromised and AIDS patients** **ii) Primary and recurrent Varicella Zoster infection in immunocompromised and AIDS patients** **iii) Severe Kaposi Varicella Eruption (Eczema herpeticum)** **iv) Severe primary HSV infections (eg. Neonatal herpes, encephalitis, eczema herpeticum, genital herpes, gingival stomatitis, vaginal delivery with maternal vulva herpes)** **v) Severe and complicated varicella infection (eg. Encephalitis, purpura fulminans)** **vi) Severe zoster infection in paediatrics (eg. Encephalitis, purpura fulminans, immunocompromised patients and facial, sacral and motor zoster)**		
3.	Acyclovir 800mg Tablet (7 produk berdaftar/ *Multisource*) **Kategori Preskriber**: A* **Kaedah Perolehan**: LP			
4.	Vancomycin HCl 500 mg Injection (8 produk berdaftar/ *Multisource*) **Kategori Preskriber**: A*	**INDICATION** **Only for the treatment of MRSA and CAPD peritonitis**	(i) Treatment of infections due **to susceptible gram-positive** organisms which **cannot be treated** with other agents (eg. MRSA and Enterococcus sp.)	***Added*** *and* ***streamlined*** *indication and dosage in FUKKM with registered DCA indications and product insert*

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
	Kaedah Perolehan: APPL		(ii) Treatment of **severe staphylococcal infections** in patients who **cannot receive** or who have **failed** to respond to the penicillins and cephalosporins.	
		DOSAGE Slow IV infusion, **ADULT: 500 mg over at least 60 minutes every 6 hours or 1 g over at least 100 minutes every 12 hours.** NEONATE up to 1 week, 15 mg/kg initially, then 10 mg/kg every 12 hours. INFANT 1 - 4 weeks, 15 mg/kg initially then 10 mg/kg every 8 hours. CHILD over 1 month, 10 mg/kg every 6 hours	Slow IV infusion. **ADULT: 15-20mg/kg q 8-12 hours, not to exceed 2gm per dose.** NEONATE up to 1 week, 15 mg/kg initially, then 10 mg/kg every 12 hours. INFANT 1 - 4 weeks, 15 mg/kg initially then 10 mg/kg every 8 hours. CHILD over 1 month, 10 mg/kg every 6 hours	
5.	Streptomycin Sulphate 1 g Injection (2 produk berdaftar/ *Multisource*) **Kategori Preskriber**: B **Kaedah Perolehan:** APPL	**INDICATION** Tuberculosis	i) Tuberculosis **ii) Brucellosis** **iii) Bacterial endocarditis**	***Added and streamlined*** *indications and dosage in FUKKM with* ***registered DCA indications*** *and* ***product insert***
		DOSAGE **ADULT: 15 mg/kg daily; max: 1 g daily. Reduce max daily dose to 500-750 mg in patients >40 yr. As part of an intermittent therapy: 25-30 mg/kg/day 2-3 times/wk; max: 1.5 g/dose. Not >120 g over the course of treatment should be given unless there are no other treatment options.** **CHILD: 20-40 mg/kg (max: 1 g) daily or 25-30 mg/kg (max: 1.5 g) 2-3 times wkly.**	15 mg/kg daily (Max: 1 g daily) **Dosing is according to product insert.**	
6.	Lopinavir 100 mg and Ritonavir 25 mg Tablet (1 produk berdaftar/ *Originator*) **Kategori Preskriber**: A **Kaedah Perolehan:** LP	**INDICATION** As second line protease inhibitor if intolerant to **indinavir/ ritonavir** as part of HAART regimen.	Second line treatment for HAART regimen in combination with other anti-retroviral agents	***Amended*** *indication in FUKKM with* ***registered DCA indications*** *and because* ***No registered product*** *for Indinavir/Ritonavir*

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
7.	Lopinavir 200 mg and Ritonavir 50 mg Tablet (2 produk berdaftar/ *Multisource*) **Kategori Preskriber**: A **Kaedah Perolehan:** Kontrak	**INDICATION** As second line protease inhibitor if intolerant to **indinavir/ ritonavir** as part of HAART regimen.	As second line treatment for HAART regimen in combination with other anti-retroviral agents	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
2.0 Cardiovascular System				
1.	Diltiazem HCl 30 mg Tablet (2 produk berdaftar/ *Multisource)* **Kategori Preskriber**: B **Kaedah Perolehan**: APPL	**INDICATION** Treatment of **angina pectoris** in the following cases: i) inadequate response or intolerance to beta-blockers and Isosorbide Dinitrate ii) contraindication to beta-blockers iii) coronary artery spasm	i) Treatment of angina **ii) Hypertension**	***Added and streamlined*** *indication in FUKKM with* ***registered DCA indications***
2.	Verapamil HCl 40 mg Tablet (1 produk berdaftar/ Generik*)* **Kategori Preskriber**: B **Kaedah Perolehan**: APPL	**INDICATION** i) Supraventricular tachyarrhythmias (SVT) prophylaxis ii) angina	i) Supraventricular tachyarrhythmias (SVT) prophylaxis ii) Angina **iii) Hypertension**	***Added and streamlined*** *indication and dosage in FUKKM with* ***registered DCA indications and product insert***
		DOSAGE ADULT: 40 - 80 mg 3-4 times daily. In oral long term therapy, max: 480 mg daily	i) SVT:120-480mg in divided doses. ii) Angina:80mg 3 times daily (max 120mg times daily) iii) Hypertension: 40 - 80 mg 3-4 times daily. In oral long term therapy, max: 480 mg daily.	
3.	Glyceryl Trinitrate 5 mg/ml Injection (1 produk berdaftar/ Generik*)* **Kategori Preskriber**: A **Kaedah Perolehan:** APPL	**INDICATION** Prophylaxis and treatment of angina, left ventricular failure. **Not for direct IV injection**.	i) Prophylaxis and treatment of angina, left ventricular failure. **ii) Congestive heart failure** **ii) Control of hypertensive episodes**	***Added and streamlined*** *indication and dosage in FUKKM with* ***registered DCA indications and product insert***
		DOSAGE **Initial 5 mcg/min** delivered via infusion pump. Subsequent titration must be adjusted to clinical situation with dose increment becoming more cautious as partial response is seen.	Initial of 10-25mcg/min **Dosing is according to product insert.**	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
4.	Valsartan 80 mg Tablet (10 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A/KK **Kaedah Perolehan:** Kontrak Pusat	**INDICATION** Patients who cannot tolerate ACE inhibitors because of cough in: i) Heart failure; ii) Post myocardial infarction	Patients who cannot tolerate ACE inhibitors because of cough in: i) Heart failure ii) Post myocardial infarction iii) **Hypertension**	
		DOSAGE i) 40 mg twice daily. Uptitration to 80 mg and 160mg twice daily. Max: 320 mg in divided doses. ii) 20 mg twice daily increased over several weeks to 160mg twice daily if tolerated.	i) & ii) As per FUKKM iii) 80mg or 160mg once daily, titrate as needed based on patient response up to 320mg /day	
5.	Bisoprolol Fumarate 2.5 mg Tablet (5 produk berdaftar/ *Multisource)* **Kategori Preskriber**: B **Kaedah Perolehan**: Kontrak Pusat	**INDICATION** Treatment of stable moderate to severe congestive cardiac failure in addition to ACEI's and diuretics	**(i) Hypertension** **(ii)Coronary heart disease (angina pectoris)** (iii) Treatment of stable congestive cardiac failure in addition to ACEI's and diuretics	***Added and streamlined*** *indication and dosage in FUKKM for both strengths (2.5mg; 5mg) with* ***registered DCA indications*** *and* ***product insert***
6.	Bisoprolol Fumarate 5 mg Tablet (10 produk berdaftar/ *Multisource)* **Kategori Preskriber**: B **Kaedah Perolehan:** Kontrak Pusat	**DOSAGE** 1.25 mg once daily to 5 - 10 mg daily	1.25 mg once daily, gradually titrate to maximum tolerable dose (i) & (ii): Max: 20mg/ day (iii): Max 10mg/ day	
7.	Ticagrelor 90 mg Tablet (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A* **Kaedah Perolehan**: Kontrak Pusat	**INDICATION** a) **Patient who failed** clopidogrel readmitted to hospital with recurrent atherothrombotic event while patients are on clopidogrel. b) ACS patients with: i) STEMI - going for invasive (PCI) ii) NSTEMI/UA - intermediate to high risk (based on TIMI score) iii) Other complicated ACS cases treated either medically or invasively via PCI or CABG (risk of Stent thrombosis, 3VD etc.)	**Co-administration with aspirin**, for the prevention of atherothrombotic events: a) **Second line** treatment for patients readmitted to hospital with recurrent atherothrombotic event failing treatment with clopidogrel. b) STEMI patients going for invasive PCI c) NSTEMI/UA patients with intermediate to high risk TIMI score	***Amended and streamlined*** *indications in FUKKM based on* ***registered DCA indications***

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
			d) Other complicated ACS cases treated either medically or invasively via PCI or CABG (risk of Stent thrombosis, 3VD etc.)	
8.	Noradrenaline Acid Tartrate (Norepinephrine Bitartrate) 1 mg/ml Injection (3 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A **Kaedah Perolehan:** Kontrak Pusat	**INDICATION** Septic shock and shock where peripheral vascular resistance is low	i) For blood pressure control in certain acute hypotensive states (e.g.pheochromocytomectomy, sympathectomy, poliomyelitis, spinal anesthesia, myocardial infarction, septicemia, blood transfusion, and drug reactions). ii) As an adjunct in the treatment of cardiac arrest and profound hypotension	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
3.0 NERVOUS SYSTEM				
1.	Trifluoperazine HCl 5 mg Tablet (1 produk berdaftar/ Generik) **Kategori Preskriber**: B **Kaedah Perolehan**: APPL	**INDICATION** Psychotic disorder	i) Schizophrenia, other psychotic disorder **ii) Treatment of behavioural disorders in adults and in children**	***Added and streamlined*** *indications and dosage in FUKKM with* ***registered DCA indications and product insert***
		DOSAGE ADULT: Initially 5 mg twice daily, increase by 5 mg after 1 week, then at 3-day intervals. Maximum 40 mg/day. CHILD up to 12 years: Initially up to 5 mg daily in divided doses adjusted to response, age and body weight	ADULT: Initially 5 mg twice daily, increase by 5 mg after 1 week, then at 3-day intervals. Maximum 40 mg/day. CHILD up to 12 years: Initially up to 5 mg daily in divided doses adjusted to response, age and body weight. **Elderly reduce initial dose by at least half.**	
2.	Fluvoxamine 100 mg Tablet (1 produk berdaftar/ **Originator)* (*produk generik tidak perbaharui pendaftaran) **Kategori Preskriber**: B **Kaedah Perolehan**: Kontrak Pusat	**INDICATION** Depression	i) Depression **ii) Obsessive Compulsive Disorder**	
3.	Fluvoxamine 50 mg Tablet (3 produk berdaftar/ *Multisource)* **Kategori Preskriber**: B **Kaedah Perolehan:** Kontrak Pusat	**INDICATION** Depressive disorder		
		DOSAGE For depression, initially 50 – 100 mg daily in the evening, increased if necessary to 300 mg daily (over 150 mg in divided doses); usual maintenance dose 100 mg daily. CHILD and ADOLESCENT under 18 years not recommended	i) As per info in FUKKM ii) Starting dose is 50 mg per day for 3 – 4 days. (The effective dosage is 100-300 mg) The starting dose for children from 8 years on and adolescents is 25mg per day, preferably at bedtime. (Max: 200 mg) (>50mg divided dose)	
4.	Perphenazine 4 mg Tablet (1 produk berdaftar/ Generik) **Kategori Preskriber**: B **Kaedah Perolehan:** LP	**INDICATION** Schizophrenia and other psychoses	i) Treatment of **psychotic disorders** **ii) Used in the treatment of behavioural disorders in adults, in the aged and in children**	***Amended and added*** *indications in FUKKM based on* ***registered DCA indications***

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
5.	Topiramate 25 mg Tablet (1 produk berdaftar/ *Originator (*produk generik tidak perbaharui pendaftaran) **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	**INDICATION** Add-on therapy for intractable partial epilepsy	As adjunctive therapy for adults and children (2 years and above) with: i) partial onset seizures and generalized tonic-clonic seizures ii) seizures associated with Lennox Gastaut syndrome.	***Amended and added*** *indications and dosage in FUKKM based on* ***registered DCA indications*** *and* ***product insert***
6.	Topiramate 50 mg Tablet (4 produk berdaftar/ Multisource) **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat			
7.	Topiramate 100 mg Tablet (4 produk berdaftar/ Multisource) **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat	**DOSAGE** ADULT: Initially 25-50mg nightly for 1 week. Subsequently at wkly or bi-wkly intervals, increase dose by 25-50 to 100mg/day in 2 divided doses. CHILD aged 2 and above: Approx 5-9 mg/kg/day in 2 divided doses. Titrate at 25mg (or less, based on a range of 1-3mg/kg/day) nightly for the 1st week. Subsequently at 1 or 2 wkly intervals, with increments of 1-3 mg/kg/day in 2 divided doses.	ADULT: Usual daily dose: 200-400 mg/day. CHILD: Daily doses up to 30mg/kg/day **Dosing is according to product insert.**	
8.	Haloperidol 5 mg Tablet (1 produk berdaftar/ Generik) **Kategori Preskriber**: B **Kaedah Perolehan:** LP	**INDICATION** Schizophrenia and other psychoses	i) **Psychotic disorder** – management of acute and chronic psychotic disorders including schizophrenia, manic states and drug-induced psychoses **ii) Management of aggressive and agitated patients, including patients with chronic brain syndrome or mental retardation.** **iii) Gilles de la Tourette's syndrome - for the control of tics and vocalisations of**	***Amended and added*** *indications and dosage in FUKKM based on* ***registered DCA indications*** *and* ***product insert***
9.	Haloperidol 1.5 mg Tablet (1 produk berdaftar/ Generik)			

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
	Kategori Preskriber: B **Kaedah Perolehan::** APPL		**Tourette's syndrome in children and adults.**	
		DOSAGE Adult:0.5-5 mg bid/tid, may increase up to 100 mg daily in severe or resistant cases. Usual maintenance: 3-10 mg daily. †Child: >3 yr: Initially, 25-50 mcg/kg daily in 2 divided doses, increased gradually if necessary. Max: 10 mg/day.	ADULT: moderate symptoms: 0.5mg to 2.0mg bid/tid; severe symptoms, chronic or resistant: 3.0mg to 5.0mg bid/ tid Geriatric / dehabilitated : 0.5mg to 2.0mg bid/tid maximum up to 100mg daily CHILD: 3-13 years old (15 to 40 kg): 0.5mg/day increase by 0.5mg at 5 to 7 days in bid/tid, dosing range 0.05mg/kg/day to 0.15mg/kg/day **Dosing is according to product insert.**	
10.	Haloperidol 5 mg/ml Injection (1 produk berdaftar/ Generik) **Kategori Preskriber**: B **Kaedah Perolehan:** LP	**INDICATION** Acute psychoses and mania	i) Management of **acute psychotic disorders** including schizophrenia, manic states, and drug-induced psychosis. **ii) Management of aggressive and agitated patients, including patients with chronic brain syndrome or mental retardation.**	***Amended and added*** *indications in FUKKM based on* ***registered DCA indications***
11.	Neostigmine Methylsulphate 2.5 mg/ml Injection (2 produk berdaftar/ Multisource) **Kategori Preskriber**: B **Kaedah Perolehan:** APPL	**INDICATION** i) Myasthenia gravis ii)Reversal of non-depolarising neuromuscular blockade	i) **Symptomatic treatment** of myasthenia gravis where oral therapy is impractical ii) Reversal of the effects of non-depolarizing neuromuscular blockade **iii)The management of post-operative distension, paralytic ileus and urinary retention, where mechanical obstruction has been out-ruled**	***Amended and added*** *indications and dosage in FUKKM based on* ***registered DCA indications*** *and* ***product insert***
		DOSAGE i) ADULT: 1 - 2.5 mg at suitable intervals by SC, IM or IV. Usual total daily dose 5 - 20 mg. **CHILD: 200 - 500 mcg** at suitable intervals throughout the day. NEONATE: 50 - 250 mcg every 4 hours	i) ADULT: 1 - 2.5 mg at suitable intervals by SC, IM or IV. Usual total daily dose 5 - 20 mg. **CHILD: 0.1mg IM. Titrated in the range of 0.05mg - 0.25mg.** NEONATE: 50 - 250 mcg every 4 hours	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
		ii) By IV injection over 1 minute, 50 - 70 mcg/kg (**maximum 5 mg**) after or with atropine sulphate 0.6 - 1.2 mg	ii) By IV injection over 1 minute, 50 - 70 mcg/kg (maximum 5 mg **and 2.5mg for children**) after or with atropine sulphate 0.6 - 1.2 mg **iii) Adults: SC or IM 0.5 - 2.5mg. Children: SC or IM 0.125mg - 1mg**	
12.	Sodium Valproate 200 mg/5 ml Syrup (3 produk berdaftar/ Multisource) **Kategori Preskriber**: B **Kaedah Perolehan:** Kontrak Pusat	**INDICATION** Epilepsy	**i) Treatment of generalized or partial epilepsy.** **ii) Treatment and prevention of mania associated with bipolar disorder**	***Amended and added*** *indications in FUKKM based on* ***registered DCA indications***
13.	Olanzapine 5 mg Tablet (4 produk berdaftar/ Multisource) **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat	**INDICATION** i) Acute and maintenance treatment of schizophrenia and other psychoses where positive and or negative symptoms are prominent ii) Short-term use for acute mania episodes associated with Bipolar 1 disorder	i) Acute and maintenance treatment of schizophrenia and other psychoses where positive and or negative symptoms are prominent ii) Short-term use for acute mania episodes associated with Bipolar 1 disorder **iii) Prevention of recurrence of manic, mixed or depressive episodes in Bipolar I Disorder.**	***Added*** *indications in FUKKM based on* ***registered DCA indications***
14.	Olanzapine 10 mg Tablet (6 produk berdaftar/ Multisource) **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat			
15.	Olanzapine 5mg Disintegrating Tablet (6 produk berdaftar/ Multisource) **Kategori Preskriber**: A* **Kaedah Perolehan:** LP			
16.	Olanzapine 5mg Disintegrating Tablet (8 produk berdaftar/ Multisource) **Kategori Preskriber**: A* **Kaedah Perolehan:** LP			

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
17.	Ropinirole HCl 0.25 mg Tablet (1 produk berdaftar/ **Originator)* (*produk generik tidak perbaharui pendaftaran*)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	**INDICATION** Parkinson disease in younger patients and patients with dyskinesias, especially peak dose dyskinesias	i) Treatment of idiopathic Parkinson's disease. It may be used as monotherapy or in combination with levodopa **ii) Treatment of restless leg syndrome**	***Amended and added*** *indications and dosage in FUKKM based on* ***registered DCA indications*** *and* ***product insert***
18.	Ropinirole HCl 1 mg Tablet (1 produk berdaftar/ **Originator)* (*produk generik tidak perbaharui pendaftaran*)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	**DOSAGE** 0.25 mg 3 times daily gradually increasing till adequate response obtained up to a maximum of 24 mg/day. Most patients need 3-9 mg/day	i) 0.25 mg 3 times daily gradually increasing till adequate response obtained up to a maximum of 24 mg/day. Most patients need 3-9 mg/day **ii) Initial: 0.25mg ON for 2 days then increased if tolerated to 0.5mg ON. Further dose increment of 0.5mg/week can be made until optimal response is achieved**	
19.	Sertraline HCl 50 mg Tablet (9 produk berdaftar/ *Multisource)* **Kategori Preskriber**: B **Kaedah Perolehan:** LP	**INDICATION** Major depression, obsessive-compulsive disorder (OCD), panic disorder	i) Major depression, obsessive-compulsive disorder (OCD), panic disorder **ii) Social anxiety disorder (social phobia)**	
		DOSAGE Depression, obsessive-compulsive disorder: 50 mg/day, may increase in steps of 50mg at weekly interval, max:200mg/day. Panic disorder: Initially 25 mg/day. After 1 week, increase dose to 50 mg/day. All dose changes should be made at intervals of more than 1 week, max: 200 mg/day	i) As per info in FUKKM **ii) Therapy should be initiated at 25 mg/day. After one week, the dose should be increased to 50 mg once daily. Patients not responding to a 50 mg dose may benefit from dose increases. Dose changes should be made at intervals of at least one week, up to a maximum of 200 mg/day.**	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
20.	Pramipexole Dihydrochloride 0.125 mg Tablet (2 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat	**INDICATION** Treatment for signs and symptoms of advanced idiopathic Parkinson's disease. It may be used as monotherapy or in combination with levodopa	i) Treatment for signs and symptoms of advanced idiopathic Parkinson's disease. It may be used as monotherapy or in combination with levodopa **ii) Symptomatic treatment of idiopathic Restless Legs Syndrome.**	***Added and streamlined*** *indications in FUKKM with* ***registered DCA indications***
21.	Pramipexole Dihydrochloride 1 mg Tablet (3 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat			
22.	Duloxetine 30 mg Capsule (5 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	**INDICATION** Major depressive disorder, diabetic peripheral neuropathic pain	i) Major depressive disorder ii) Diabetic peripheral neuropathic pain **iii) Generalised Anxiety Disorder**	***Amended and added*** *indications and dosage in FUKKM based on* ***registered DCA indications*** *and* ***product insert***
23.	Duloxetine 60 mg Capsule (5 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	**DOSAGE** ADULT: 60 mg once daily up to a maximum dose of 120mg/day (in divided doses) CHILD and ADOLESCENT under 18 years not recommended	i) – ii) As per info in FUKKM **iii) Generalised Anxiety:** **Initial dose: 30 mg OD with or without food** **Maintenance dose: 60 mg OD**	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
24.	Pregabalin 50 mg Capsule (5 produk berdaftar/ *Multisource)*	**Strength not listed in FUKKM** **Current Indications for 75mg & 150mg** i) Neuropathic pain ii) Fibromyalgia iii) Epilepsy	Pregabalin 50 mg Capsules **INDICATIONS** i) Neuropathic pain ii) Fibromyalgia iii) Epilepsy	***Added new strength*** *in FUKKM for dosing flexibility*
25.	Pregabalin 75 mg Capsule (9 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat	**INDICATION** i) Second line treatment of neuropathic pain in patients who do not response to first line drugs ii) Fibromyalgia	i) Neuropathic pain ii) Fibromyalgia **iii) Epilepsy**	***Added and streamlined*** *indications and dosage in FUKKM based on* ***registered DCA indications*** *and* ***product insert***
26.	Pregabalin 150 mg Capsule (8 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** Kontrak Pusat	**DOSAGE** i) Initially, 75 mg twice daily. May be increased to 150 mg twice daily after 3-7 days. Max: 600 mg/day after an additional 7-day interval ii) Initially, 75 mg twice daily. May be increased to 150 mg twice daily within 1 week or 225 mg twice daily. Max: 450 mg/day	*The dose range is 150 to 600 mg per day given in either two or three divided doses.* *Dosing is according to Product Insert***.**	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
27.	Morphine Sulphate 10 mg/ml Injection (4 produk berdaftar/ *Multisource)* **Kategori Preskriber**: B **Kaedah Perolehan:** APPL	**INDICATION** For moderate to severe pain especially that associated with neoplastic disease	i) For moderate to severe pain especially that associated with neoplastic disease **ii) As an analgesic adjunct in general anaesthesia.**	***Added and streamlined*** *indications and dosage in FUKKM based on* ***registered DCA indications*** *and* ***product insert*** ***Note:*** *Dosing in product insert is general, not specific to indication.*
		DOSAGE ADULT: 5-20mg SC or IM every 4 hours in terminal pain CHILD: Up to 1 month: 0.15 mg/kg body weight; 1 - 12 months: 0.2 mg/kg body weight; 1 - 5 years: 2.5 - 5 mg ; 6 - 12 years: 5 - 10 mg	ADULT: 5 to 20 mg every 4 hours, intravenously (IV or IM), **2.5 to 15mg should be given by slow injection.** **CHILD:** **- Adjusted according to body weight, 0.1 – 0.2 mg /kg every 4 hours. No dose should exceed 15 mg.** **- Analgesic** **i) subcutaneous, 100 mg to 200 mg (0.1 to 0.2 mg) per kg of body weight every four hours as needed, not to exceed 15mg per dose.** **ii) Intravenous, 50 to 100 mcg (0.05 mg to 0.1 mg) per kg of body weight, administered very slowly.**	
28.	Phenobarbitone Sodium 200 mg/ml Injection (1 produk berdaftar/ Generik*)* **Kategori Preskriber**: B **Kaedah Perolehan:** LP	**INDICATION** Status Epilepticus	**All forms of epilepsy except absence seizures.**	***Amended*** *indications and dosage in FUKKM based on* ***registered DCA indications*** *and* ***product insert***
		DOSAGE ADULT: 10 mg/kg IV at a rate of not faster than 100 mg/minute. Initial maximum dose does not exceeding 1 gm. Daily maintenance of 1 - 4 mg/kg/day. CHILD: 10 - 20 mg/kg/dose loading dose, followed by repeated doses at 10 mg/kg/dose (strictly in ICU setting). Maintenance 5 - 8 mg/kg/day	ADULT: 10 mg/kg IV at a rate of not faster than 100 mg/minute. Initial maximum dose does not exceeding 1 gm. Daily maintenance of 1 - 4 mg/kg/day. **CHILD: 3- 5mg per kg body weight as a single dose by intramuscular injection. Dosing is according to product insert.**	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS / KEKUATAN		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
29.	Carbamazepine 200 mg CR Tablet (2 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A **Kaedah Perolehan**: Kontrak Pusat	**INDICATION** Epilepsy	i) Epilepsy **ii) Trigeminal Neuralgia** **iii) Idiopathic glossopharyngeal neuralgia** **iv) Acute mania and maintenance of bipolar affective disorder to prevent or attenuate recurrence**	***Added and streamlined*** *indication in FUKKM with* ***registered DCA indications***
30.	Carbamazepine 400 mg CR Tablet (2 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A **Kaedah Perolehan**: Kontrak Pusat			

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER / KAEDAH PEROLEHAN	INDIKASI / DOS		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
4.0 ANTINEOPLASTIC and IMMUNOMODULATING AGENTS				
1.	Epirubicin 2mg/mL Injection (8 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** APPL	**INDICATION** i. Solid tumour ii. Non-Hodgkin's lymphoma iii. Leukaemia (ALL induction)	i. Solid tumour ii. Non-Hodgkin's lymphoma iii. Leukaemia (ALL induction) **iv. Lymphoma**	***Added and streamlined*** *indication in FUKKM with* ***registered DCA indications.***
2.	Paclitaxel 6mg/mL Injection (6 produk berdaftar/ Generik*)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	**INDICATION** **i) Treatment of recurrent breast cancer, after failure of anthracycline-based chemotherapy** **ii) Primary adjuvant therapy in advanced ovarian cancer in combination with cisplatin** **iii) Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) in chemo naive patients in combination with platinum compounds**	i) Breast carcinoma: Initial treatment of advanced or metastatic and also second line after failure of standard therapy. ii) Ovarian carcinoma: First Line in combination with a platinum compound for advanced metastatic carcinoma of the ovary; Second line for advanced metastatic carcinoma of the ovary iii) Non-small cell lung carcinoma: First line in combination with platinum compound or as single agent	
3.	Pemetrexed Disodium 100mg Injection (7 produk berdaftar/ Generik*)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	**INDICATION** In combination with Cisplatin for the 2nd line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology	i) In combination with Cisplatin for the 2nd line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology **ii) Malignant pleural mesothelioma** ***In combination with platinum compound for first line treatment***	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER/ KAEDAH PEROLEHAN	INDIKASI / DOS		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
5.0 MUSCULOSKELETAL SYSTEM				
1.	Clostridium botulinum type A 100IU Injection (3 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	**INDICATION** i) Focal dystonias ii) Hemifacial spasm iii) Spasticity including cerebral palsy	i) Focal dystonias ii) Hemifacial spasm iii) Spasticity including cerebral palsy **iv) Neurogenic bladder**	***Added and streamlined*** *indication in FUKKM with* ***registered DCA indications****.*
2.	Alendronate 70mg Tablet (3 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A* **Kaedah Perolehan:** LP	**INDICATION** Osteoporosis in postmenopausal women with a history of vertebral fracture and whom oestrogen replacement therapy is contraindicated. Review treatment after 2 years and if there is positive response, treatment may be continued up to 5 years and then re-evaluate. Treatment should be stopped if there is no positive response after 5 years. Otherwise, patient needs to be given drug holiday for 1 to 2 years and then continue treatment shall the benefit outweigh the risk.	Osteoporosis (Male)	

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER/ KAEDAH PEROLEHAN	INDIKASI / DOS		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
6.0 BLOOD and BLOOD FORMING ORGANS				
1.	Iron (III)-Hydroxide Polymaltose Complex (IPC) 100 mg Iron and 0.35mg Folic Acid Chewable Tab (1 produk berdaftar/ *Originator)* **Kategori Preskriber**: A/KK **Kaedah Perolehan:** LP	**INDICATION** Treatment of latent and manifest iron deficiency and prevention of iron and folic acid deficiency before, during after pregnancy (during lactation)	Treatment of iron deficiency without anaemia and iron deficiency anaemia	***Amended and streamlined*** *indication in FUKKM with* ***registered DCA indications****.*
2.	Erythropoietin Human Recombinant IU Injection 1. 1,000 IU (A*, LP) 2. 2,000 IU (A, Kontrak Pusat) 3. 3,000 IU (A*, LP) 4. 4,000 IU (A, APPL) 5. 10,000 IU (A*, LP) (3 produk berdaftar/ *Multisource)*	**DOSAGE** **Anaemia in cancer (non-myeloid malignancies) with concomitant chemotherapy** ADULT: by SC injection (max. 1 ml per injection site), initially 150 units/kg 3 times weekly, increased if appropriate rise in haemoglobin not achieved after 4 weeks to 300 units/kg 3 times weekly. Discontinue if inadequate response after 4 weeks at higher dose	a) EPO Alfa: 150IU/kg three times weekly or 40,000IU once weekly b) EPO Beta: 450IU/kg once weekly or 30,000 IU once weekly **Dosing is according to product insert.**	***Streamlined*** *dosage in FUKKM with* ***product insert.***

BIL.	NAMA GENERIK/ KATEGORI PRESKRIBER/ KAEDAH PEROLEHAN	INDIKASI / DOS		JUSTIFIKASI / TINDAKAN
		ASAL	BARU	
7.0 SENSORY ORGANS				
1.	Timolol 0.5% Eye Drops (6 produk berdaftar/ *Multisource)* **Kategori Preskriber**: A **Kaedah Perolehan:** APPL	**DOSAGE** 1 drop for once daily or 2 times daily depending on manufacturer's recommendation.	*One drop in the affected eye(s)* ***twice daily*** *or as directed by physician*	***Amended and streamlined*** *dosage in FUKKM with* ***product insert.***