PINDAAN/TAMBAHAN KEPADA FORMULARI UBAT KKM (FUKKM) BIL. 2 TAHUN 2021

BIL.	NAMA UBAT	LAMPIRAN
PENYENARAIAN UBAT BARU		
1.	*Emicizumab 30mg/ml & 150mg/ml solution for injection*	A1
2.	*Ferric derisomaltose 100 mg/ml solution for injection/infusion*	
TAMBAH BENTUK DOSEJ/ FORMULASI/ KEKUATAN		
1.	*Somatropin 6mg solution for injection*	A2
2.	*Aripiprazole 400 mg powder and solvent for prolonged-release suspension for injection*	
3.	*Abacavir Sulphate 300mg tablet*	
4.	*Menotrophin highly purified 150IU injection*	
PINDAAN KATEGORI PRESKRIBER		
1.	*Betahistine dihydrochloride 24mg tablet*	A3
2.	*Atorvastatin 20mg & 40mg tablets*	
3.	*Esomeprazole 20 mg & 40mg capsule*	
4.	*Pantoprazole 40 mg tablet*	
5.	*Pantoprazole 40 mg injection*	
PEMANSUHAN DARIPADA FUKKM		
1.	*Aprotinin 10,000 KIU/ml injection*	A4
2.	*Betahistine dihydrochloride 8 mg tablet*	
3.	*Betahistine dihydrochloride 16 mg tablet*	
4.	*Dimenhydrinate 50mg tablet*	
5.	*Somatropin 12 mg (36IU) injection*	
PENGEMASKINIAN MAKLUMAT KEPADA UBAT-UBATAN DALAM FUKKM		
1.	Pengemaskinian Maklumat Indikasi dan Dos ***Nota:*** • *Pemurnian maklumat ubat dalam FUKKM adalah berdasarkan justifikasi "To streamline indications and dosage according to DCA indications and product insert."* • *Maklumat dosing dalam FUKKM adalah untuk rujukan sahaja. Pihak fasiliti haruslah menyemak sisip bungkusan (package/product insert) dan protokol yang berkaitan.*	B1

LAMPIRAN A1

UBAT BARU YANG DILULUSKAN PENYENARAIAN KE DALAM FUKKM

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
1.	*Emicizumab 30mg/ml & 150mg/ml solution for Injection* *MDC:* *30mg/mL:* *B02BX06-000-P30-01-XXX* *150mg/mL:* *B02BX06-000-P30-02-XXX* *Cost/unit (RM):* *30mg/1ml: RM 3,593 /vial* *60mg/0.4ml: RM 7,186 /vial* *105mg/0.7ml: RM 12,576 /vial* *150mg/1ml: RM 17,966 /vial* *Prescriber Category:* *A**	*Approved Indication(s):* *For routine prophylaxis of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors* *Prescribing restriction:* *To be prescribed by consultant haematologists only* *Dose:* *3 mg/kg once weekly for the first 4 weeks (loading dose), followed by maintenance dose of either 1.5 mg/kg once weekly, 3 mg/kg every two weeks, or 6 mg/kg every four weeks* *Precaution(s):* *Thrombotic microangiopathy associated with emicizumab and activated prothrombin complex concentrate, thromboembolism associated with emicizumab and activated prothrombin complex concentrate, use of bypassing agents in patients receiving emicizumab prophylaxis and effects of emicizumab on coagulation tests* *Adverse reaction(s):* *Headache, arthralgia, injection site reaction, diarrhea, myalgia, pyrexia* *Contraindication(s):* *Hypersensitivity to the active substance or to any of the excipients* *Interaction(s):* *No adequate or well-controlled drug-drug interaction studies have been conducted with Emicizumab, Possible: rFVIIa or FVIII*
2.	*Ferric derisomaltose 100 mg/ml solution for injection /infusion* *MDC:* *B03AC00-000-P30-01-XXX* *Cost/unit (RM):* • *5ml: RM290.00 /vial* • *10ml: RM 525.00 /vial* *Prescriber Category:* *A**	*Approved Indication(s):* *Indicated for the treatment of iron deficiency in the following conditions:* • *when oral iron preparations are ineffective or cannot be used* • *where there is a clinical need to deliver iron rapidly* *The diagnosis must be based on laboratory tests.* *Prescribing restriction:* *To be prescribed by haematologists only*

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
		Dose administration: ***Intravenous bolus injection:*** *Up to 500 mg up to three times a week at an administration rate of up to 250 mg iron/minute.* ***Intravenous drip infusion:*** *Up to 20 mg iron/kg body weight or as weekly infusions until the cumulative iron dose has been administered.* *If the cumulative iron dose exceeds 20 mg iron/kg body weight, the dose must be split in two administrations with an interval of at least one week.* *Precaution(s):* *Hypersensitivity reactions, allergies (including drug allergies), patients with immune or inflammatory conditions, use with caution in case of acute or chronic infection, hypotensive episodes* *Adverse reaction(s):* *Hypersensitivity reactions (e.g. anaphylactoid reactions, urticaria, rashes, itching, nausea and shivering), delayed reactions (e.g. arthralgia, myalgia and fever), exacerbation of joint pain in rheumatoid arthritis, local reactions may cause pain and inflammation at or near injection site and a local phlebitic reaction.* *Contraindication(s):* • *Hypersensitivity to the active substance, to ferric derisomaltose or any of its excipients.* • *Known serious hypersensitivity to other parenteral iron products.* • *Non-iron deficiency anaemia (e.g. haemolytic anaemia)* • *Iron overload or disturbances in utilisation of iron (e.g. haemochromatosis, haemosiderosis)* • *Decompensated liver cirrhosis and hepatitis* *Interaction(s):* *Oral iron preparations*

LAMPIRAN A2

TAMBAHAN BENTUK DOSEJ/ FORMULASI/ KEKUATAN YANG DILULUSKAN PENYENARAIAN KE DALAM FUKKM

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
1.	*Somatropin 8mg solution for injection*	*Approved to add new strength:* *Somatropin 6mg solution for injection* MDC: *H01AC01-000-P30-04-XXX* *Cost/unit (RM):* *RM 345.00 / cartridge* *Prescriber Category*: *A**	*Approved Indication(s):* *i) Growth failure due to inadequate endogenous growth hormone* *ii) Growth failure in girls due to gonadal dysgenesis (Turner syndrome)* *iii) Growth failure in short children born small gestational age (SGA)* *Prescribing restriction: -* *For paediatric consultants / specialists use only* *This medicine is for the following patients who will require the specific features of the supplied device for treatment optimization:* *1. Young infants or toddlers who need very precise dose administration (for example 0.19 mg, 0.27 mg and etc.)* *2. Other older patients who are unable to tolerate or who have poor medication compliance with other growth hormone preparations* *Dose:* *i) 0.025-0.035mg/kg/day* *ii) 0.045-0.05mg/kg/day* *iii) 0.035 mg/kg/day* *Precaution(s):* *Neoplasm, Prader-Willi Syndrome, Leukaemia, insulin insensitivity, retinopathy, thyroid function, benign intracranial hypertension, pancreatitis, scoliosis, antibodies, slipped capital femoral epiphysis, growth failure due to chronic renal failure, children born small for*

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
			gestational age, fluid retention, acute critical illness, interaction with glucocorticoids, use with oral oestrogen therapy, pregnancy, breastfeeding *<u>Adverse reaction(s):</u>* *Headache (isolated), injection site reactions, localised lipoatrophy,* *<u>Contraindication(s):</u>* *Hypersensitivity to the active substance or to any of the excipients; children with closed epiphyses, any evidence of activity of a tumour, proliferative or pre-proliferative diabetic retinopathy.* *Patients with acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions should not be treated with somatropin.* *In children with chronic renal disease, treatment with somatropin should be discontinued at renal transplantation.* *<u>Interaction(s):</u>* *Oral oestrogen therapy. Treatment with glucocorticoids / high doses of corticosteroid may inhibit growth-promoting effects of somatropin.*
2.	*Aripiprazole 10mg; 15mg tablet*	*<u>Approved to add new dosage form:</u>* *Aripiprazole 400 mg powder and solvent for prolonged-release suspension for injection* *<u>MDC:</u>* *N05AX12-010-P20-01-XXX* *<u>Cost/unit (RM):</u>* *RM 700.40/ vial*	*<u>Approved Indication(s):</u>* *Maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole* *<u>Prescribing Restriction(s):</u> -* *As second-line therapy among patients with poor or uncertain adherence to oral antipsychotics.* *<u>Dose:</u>* *Recommended starting and maintenance dose is 400 mg to be*

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
		Prescriber Category: A*	*administered once monthly as a single injection (no sooner than 26 days after the previous injection).* *After the first injection, treatment with 10 mg to 20 mg oral aripiprazole should be continued for 14 consecutive days to maintain therapeutic aripiprazole concentrations during initiation of therapy.* *Precaution(s):* *Suicidality, cardiovascular disorders, QT prolongation, tardive dyskinesia, Neuroleptic Malignant Syndrome (NMS), seizure, elderly patients with dementia-related psychosis, hyperglycaemia and diabetes mellitus, hypersensitivity, weight gain, dysphagia, pathological gambling and impulse-control disorders, falls, orthostatic hypotension, severe hepatic impairment, known CYP2D6 poor metabolisers, pregnancy and breast-feeding. May impair ability to drive and use machines.* *Adverse reaction(s):* *Weight increased, diabetes mellitus, weight decreased, agitation, anxiety, restlessness, insomnia, extrapyramidal disorder, akathisia, tremor, dyskinesia, sedation, somnolence, dizziness, headache, dry mouth, musculoskeletal stiffness, erectile dysfunction, injection site pain, injection site induration, fatigue, blood creatinine phosphokinase increased.* *Contraindication(s):* *Hypersensitivity to the aripiprazole or to any of the excipients.*

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
			Interaction(s): *Antihypertensive medicinal products with α1-adrenergic receptor antagonism properties, alcohol or other CNS medicinal products with overlapping adverse reactions such as sedation, medicinal products known to cause QT prolongation or electrolyte imbalance, quinidine and strong CYP2D6 inhibitors, ketoconazole and other strong CYP3A4 inhibitors, carbamazepine and other CYP3A4 inducers, serotonergic medicinal products.*
3.	*Abacavir sulphate 600 mg and lamivudine 300 mg tablet*	*Approved to add new formulation* *Abacavir sulphate 300mg tablet* *MDC:* *J05AF06-183-T10-01-XXX* *Cost/unit (RM):* *Market price* *Prescriber Category:* A*	*Approved Indication(s):* *Antiretroviral combination therapy of HIV infection in adults and adolescents from 12 years of age.* *Prescribing Restriction(s):* - *i. Patients unsuitable or failed other HAART treatment* *ii. Patients who have renal impairment (CrCl < 50ml/min) when Abacavir and Lamivudine fixed-dose combination is not recommended* *Dose:* *Adult:* *300mg twice daily or 600mg daily* *Children:* *i. Weighing 14 to <20kg: one-half of a scored abacavir tablet twice daily* *ii. Weighing ≥20kg to <25kg: one-half of a scored abacavir tablet in the morning and one whole tablet in the evening* *iii. Weighing at least 25kg: according to adult dose*

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
			Precaution(s): *Hypersensitivity, lactic acidosis/ severe hepatomegaly with steatosis, elevated serum lipids and blood glucose, immune reconstitution syndrome, opportunistic infections, transmission of infection, myocardial infarction* *Adverse reaction(s):* *Nausea, vomiting, diarrhoea, fever, lethargy, fatigue, rash, anorexia, headache, hyperlactatemia, pancreatitis, lactic acidosis, rash, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis* *Contraindication(s):* *Hypersensitivity reaction to the active substance or to any excipients* *Interaction(s):* *Ribavirin, ethanol, methadone and retinoids*
4.	*Menotrophin, highly purified 75 IU injection* *Menotrophin, highly purified 600 IU injection*	*Approved to add new strength:* *Menotrophin, highly purified 150 IU injection* *MDC:* *G03GA02-954-P40-02-XXX* *Cost/unit (RM):* *RM 114.00 / vial* *Prescriber Category:* A*	*Approved Indication(s):* *i) Anovulation in women who have been unresponsive to treatment with clomiphene citrate* *ii) Stimulation of follicle growth as part of an assisted reproductive technology (ART)* *Prescribing Restriction(s): -* *None* *Dose:* *As stated in the formulary for the existing alternatives* *Precaution(s):* *Discontinue if the ovaries become enlarged or abdominal pain occurs. Special care should be exercised to monitor for pregnancy. During ovulation induction therapy and for a*

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
			two-week period after therapy, patients should be examined every other day for signs of excessive ovarian stimulation. Multiple births can occur *<u>Adverse reaction(s):</u>* *Tumours of the pituitary gland or hypothalamus, ovarian, uterine or mammary carcinoma, pregnancy and lactation, gynaecological haemorrhage of unknown aetiology, hypersensitivity to the active substance or any of the excipients used in the formulation, ovarian cysts or enlarged ovaries not due to polycystic ovarian disease, primary ovarian failure.* *<u>Contraindication(s):</u>* *Adnexal torsion (with ovarian enlargement), ovarian cysts, flu-like symptoms, pulmonary/ vascular complications, ovarian hyperstimulation syndrome* *<u>Interaction(s):</u>* *Not known*

LAMPIRAN A3

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

BIL	NAMA GENERIK	KETERANGAN PINDAAN
1.	*Betahistine dihydrochloride 24mg tablet*	*Change in the prescriber category from A* to A/KK* *Cost/unit (RM):* *RM 0.18 /tab (Government Contract)* *Prescribing restriction:* *Diagnosis of Meniere's Syndrome or Vestibular Vertigo has to be confirmed by Otorhinolaryngologist*
2.	*Atorvastatin 20mg & 40mg tablet*	*Change in the prescriber category from A/KK to B* *Cost/unit (RM):* *20mg tablet: RM 0.129/ tablet (APPL)* *40mg tablet: RM 0.143/tablet (Government Contract)* *Prescribing restriction:* *None*
3.	*Esomeprazole 20 mg & 40mg capsule*	*Change in the prescriber category from A* to A* *Cost/unit (RM):* *20mg: RM 0.33 / capsule (Government contract)* *40mg: RM 0.48 / capsule (Government contract)* *Prescribing restriction / Line of therapy:* • *First-line therapy for patients on Ryle's tube or unable to tolerate oral therapy* • *Second-line therapy for patients who are not suitable to take or did not respond well to pantoprazole despite optimal duration of treatment*
4.	*Pantoprazole 40 mg tablet*	*Change in the prescriber category from A/KK to B* *Cost/unit (RM):* *RM 0.19 / tablet (APPL)* *Prescribing restriction in Primary Care Facilities:* *None*

BIL	NAMA GENERIK	KETERANGAN PINDAAN
5.	*Pantoprazole 40 mg injection*	*Change in the prescriber category from A* to A/KK* *<u>Cost/unit (RM):</u>* *RM 3.71 / vial (Government contract)* *<u>Amended indications:</u>* *Short term use for symptomatic improvement and healing of gastrointestinal diseases which require a reduction in acid secretion:* • *Duodenal ulcer* • *Gastric ulcer* • *Moderate and severe reflux esophagitis* • *Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions*

Nota:

A* Pakar Perunding / Pakar bagi Indikasi yang Spesifik sahaja
A Pakar Perunding / Pakar
A/KK Pakar Perunding / Pakar / Pakar Perubatan Keluarga
B Pakar Perunding / Pakar / Pakar Perubatan Keluarga / Pegawai Perubatan
C Pakar Perunding / Pakar / Pakar Perubatan Keluarga / Pegawai Perubatan / #Anggota Paramedik
C+ Pakar Perunding / Pakar / Pakar Perubatan Keluarga / Pegawai Perubatan / #Anggota Paramedik/ #Anggota Paramedik Perbidanan

Kumpulan Paramedik: Hanya boleh membekalkan ubat dengan/tanpa preskripsi dan tidak dibenarkan untuk menulis preskripsi berdasarkan surat Pemberian Kuasa di bawah Peraturan 23A [No. Ruj: KKM.600-12/4/6 Jld. 2 (19) bertarikh 31 Oktober 2018].

LAMPIRAN A4

UBAT-UBATAN YANG DIMANSUHKAN DARIPADA FUKKM

BIL	NAMA GENERIK	JUSTIFIKASI PEMANSUHAN	ALTERNATIF DALAM FUKKM
1.	*Aprotinin 10,000 KIU/ml Injection*	1. Tiada produk berdaftar 2. Tiada data penggunaan sejak 2018 3. Terdapat alternatif dalam FUKKM	*Cardioplegia solution containing potassium chloride, magnesium chloride & procaine HCl*
2.	*Betahistine dihydrochloride 8 mg tablet*	1. Tiada di pasaran 2. Tiada sejarah penggunaan sejak 2019 3. Terdapat alternatif dalam FUKKM	*Betahistine dihydrochloride 24 mg tablet*
3.	*Betahistine dihydrochloride 16 mg tablet*	1. Tiada di pasaran 2. Terdapat alternatif dalam FUKKM	*Betahistine dihydrochloride 24 mg tablet*
4.	*Dimenhydrinate tablet 50mg*	1. Tiada sejarah penggunaan sejak 2019 2. Terdapat alternatif dalam FUKKM	*Betahistine dihydrochloride 24 mg tablet*
5.	*Somatropin 12 mg (36IU) injection*	1. Penggunaan terlalu rendah 2. Terdapat alternatif dalam FUKKM	*Somatropin 5mg injection* *Somatropin 6mg injection* *Somatropin 10 mg injection*

PENGEMASKINIAN MAKLUMAT INDIKASI DAN DOS

Justifikasi penggunaan penyataan *"Dosing is individualised and according to product insert / protocol"*:

• *Dosing* ubat perlu **disesuaikan dengan keadaan pesakit** dan terdapat pelbagai **regimen *dosing***

• *Dosing* adalah **berbeza mengikut produk** berdasarkan pendaftarannya dengan Pihak Berkuasa Kawalan Dadah (PBKD). Pihak fasiliti adalah disarankan untuk menyemak sisip bungkusan (package insert) sekiranya terdapat pertukaran jenama produk yang digunakan di fasiliti

• Memberi **fleksibiliti** kepada preskriber untuk menggunakan *dosing* yang disarankan dalam garis panduan / protokol

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
1.0 ANTINEOPLASTIC and IMMUNOMODULATING AGENTS			
1.	Bortezomib 3.5 mg Injection **Kategori Preskriber:** A* **Kaedah Perolehan:** Kontrak Pusat	***INDICATION*** *i) Treatment of multiple myeloma in* ***patient who have received at least one prior therapy.*** ***ii) For use in combination with conventional therapy for the treatment of previously untreated multiple myeloma patients who are not eligible for haematopoietic stem cell transplantation.***	***Treatment of multiple myeloma***
		DOSING *1.3 mg/ m²/dose given as IV bolus injection twice weekly for two weeks (days 1, 4, 8, and 11) followed by a 10- day rest period (days 12-21). At least 3 days should elapse between consecutive doses of bortezomib*	***1.3 mg/m² body surface area twice weekly for two weeks on days 1, 4, 8, and 11 in a 21-day treatment cycle. At least 3 days should elapse between consecutive doses of bortezomib.***
2.	Pemetrexed Disodium 100 mg Injection **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***
3.	Pemetrexed Disodium 500 mg Injection **Kategori Preskriber:** A* **Kaedah Perolehan:** Kontrak Pusat		
2a. 3a.	Pemetrexed Disodium 100 mg Injection Pemetrexed Disodium 500 mg Injection	***DOSING*** *Initial therapy 500 mg/m² IV over 10 minutes on day 1, followed 30 minutes later by cisplatin 75 mg/m² infused IV over 2 hours; repeat cycle every 21-days.* ***Prior chemotherapy: 500 mg/m(2) IV, as a single-agent, over 10 minutes on day 1 of each 21-day cycle***	*Initial therapy 500 mg/m² IV over 10 minutes on day 1, followed 30 minutes later by cisplatin 75 mg/m² infused IV over 2 hours; repeat cycle every 21-days.* ***Dosing is according to product insert / protocol.***

4.	Zoledronic Acid 4 mg Injection **Kategori Preskriber:** A* **Kaedah Perolehan:** Kontrak Pusat	***DOSING*** *i) & (ii): 4 mg reconstituted and should be given as a 15 minutes IV infusion every 3-4 weeks* *iii) 4mg reconstituted and should be given as a 15- minute IV infusion every 12 weeks (as advised in MaHTAS 2018 Report)*	***i) 4mg single dose*** ***ii) 4mg every 3-4 weeks*** *iii) 4mg reconstituted and should be given as a 15- minute IV infusion every 12 weeks (as advised in MaHTAS 2018 Report)*
2.0 MUSCULO-SKELETAL SYSTEM			
1.	Alendronate Sodium 70 mg and Cholecalciferol 5600 IU Tablet **Kategori Preskriber:** A* **Kaedah Perolehan:** Kontrak Pusat	***INDICATION*** *Osteoporosis in postmenopausal women with a history of vertebral fracture and whom oestrogen replacement therapy is contraindicated.*	*i) Osteoporosis in postmenopausal women with a history of vertebral fracture and whom oestrogen replacement therapy is contraindicated.* ***ii) Male Osteoporosis***
3.0 BLOOD AND BLOOD FORMING ORGANS			
1.	Fondaparinux Sodium 12.5 mg/ml Injection in Prefilled Syringe **Kategori Preskriber:** A* **Kaedah Perolehan:** LP	***INDICATION*** *i) Treatment of acute Deep Vein Thrombosis (DVT).* *ii) Treatment of Pulmonary Embolism (PE)*	*i) Treatment of acute Deep Vein Thrombosis (DVT)* *ii) Treatment of **acute** Pulmonary Embolism (PE)*

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
4.0 GENITO URINARY SYSTEM AND SEX HORMONES			
1.	Chorionic Gonadotrophin Human (HCG) 5000 IU Injection Kategori Preskriber: A* Kaedah Perolehan: LP	***INDICATION*** *i) Treatment of infertile women to induce ovulation* *ii) As a luteal support in controlled ovarian hyperstimulation cycles*	***In the female,*** *i) Treatment of infertile women to induce ovulation* *ii) As a luteal support in controlled ovarian hyperstimulation cycles* ***In the male,*** ***iii) Hypogonadotropic hypogonadism (also cases of idiopathic dysspermias have shown a positive response to gonadotropins),*** ***iv) Delayed puberty associated with insufficient gonadotropic pituitary function*** ***v) cryptorchidism not due to an anatomic obstruction.***
		DOSING ***i) & ii) Induction of ovulation: 5000 - 10,000 units one day following last dose of menotropin.*** ***Up to 3 repeat injections of 5000 units each may be given within the following 9 days to prevent insufficiency corpus luteum***	***i) 5,000-10 000 IU to complete treatment with an FSH-containing preparation*** ***ii) Two to three repeat injections of 1000 to 3000 IU may be given within 9 days following ovulation or embryo transfer (for example on day 3, 6 and 9 after ovulation induction)*** ***iii) 1000 - 2000 IU, two to three times per week*** ***iv) 1500 IU two to three times weekly for at least six months*** ***v) < 2 years of age: 250 IU twice weekly for six weeks*** ***< 6 years of age: 500 - 1000 IU twice weekly for six weeks*** ***> 6 years of age: 1500 IU twice weekly for six weeks.*** ***Dosing is individualised and according to product insert / protocol.***
2.	Urofollitropin (FSH) 75 IU Injection **Kategori Preskriber:** A* **Kaedah Perolehan:** LP	***INDICATION*** *Stimulation of follicular growth in infertile women*	*i) Stimulation of follicular growth in infertile women* ***ii) Male factor infertility.***
3.	Urofollitropin (FSH) 150 IU Injection **Kategori Preskriber:** A* **Kaedah Perolehan:** LP		

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
4.0 GENITO URINARY SYSTEM AND SEX HORMONES			
2a. 3a.	Urofollitropin (FSH) 75 IU Injection Urofollitropin (FSH) 150 IU Injection	***DOSING*** *To be individualized. 75 IU-150 IU daily and may be increased or decreased by up to 75 IU/day at 7 or 14-day intervals if necessary*	***i) Initial: 75IU daily for at least 7 days*** ***Titrate as needed according to follicular response.*** ***Max. 450 IU daily.*** ***In-vitro fertilisation:*** ***Initial: 150 IU daily from Cycle Day 2 or Day 3 until sufficient follicular development is attained.*** ***ii) 150 IU 3 times weekly*** ***Dosing is individualised and according to product insert / protocol.***

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
5.0 ANTI-INFECTIVES for SYSTEMIC USE			
1.	Fluconazole 50 mg Capsule **Kategori Preskriber:** A **Kaedah Perolehan:** LP	***INDICATION*** ***i) Oropharyngeal candidiasis, atrophic oral candidiasis associated with dentures, other candidal infections of mucosa*** *ii) Tinea pedis, corporis, cruris, versicolor and dermal candidiasis* ***iii) Invasive*** *candidal &* ***cryptococcal infections (including meningitis)*** ***iv) Prevention of relapse of cryptococcal meningitis in AIDS patients after completion of primary therapy*** *v) Prevention of fungal infections in* ***immunocompromised*** *patients* ***considered at risk as a consequence of HIV infections or neutropenia*** *following cytotoxic chemotherapy, radiotherapy or* ***bone marrow transplant***	***i) Cryptococcosis*** ***a) cryptococcal meningitis and infections of other sites (e.g., pulmonary, cutaneous)*** ***b) Prevention of relapse of cryptococcal meningitis in patients in AIDS after a full course of primary therapy*** ***ii) Systemic*** *candidiasis, including candidemia, disseminated candidiasis and other forms of invasive candidal infections. These include infections of the peritoneum, endocardium, eye, and pulmonary and urinary tracts.* ***iii) Mucosal*** *candidiasis.* *a) Oropharyngeal candidiasis* *b) Chronic oral atrophic candidiasis (denture sore mouth)* *c) Oesophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous candidiasis* *d) Prevention of relapse of oropharyngeal candidiasis in patients with AIDS, after a full course of primary therapy* ***iv) Genital*** *candidiasis.* *a) Vaginal candidiasis (acute or recurrent)* *b) Prophylaxis of recurrent vaginal candidiasis (three or more episodes a year)* *c) Candidal balanitis.* *v) Prevention of fungal infections in patients with malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy.* ***vi) Dermatomycosis*** *a) Tinea pedis, tinea corporis, tinea cruris and dermal Candida infections* *b) Tinea versicolor*
2.	Fluconazole 100 mg Capsule **Kategori Preskriber:** A **Kaedah Perolehan:** APPL		
3.	Fluconazole 2 mg/ml Injection **Kategori Preskriber:** A **Kaedah Perolehan:** APPL		

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
5.0 ANTI-INFECTIVES for SYSTEMIC USE			
1a. 2a. 3a.	Fluconazole 50 mg Capsule Fluconazole 100 mg Capsule Fluconazole 2 mg/ml Injection	***DOSING*** *i) **50 - 100 mg** daily for 7 - 14 days (Maximum 14 days) except in severely immunocompromised patients, treatment can be continued for longer periods. Atrophic oral candidiasis associated with dentures: 50 mg daily for 14 days. Other candidal infections of mucosa: 50 - 100 mg daily for 14 - 30 days. CHILD: 3 - 6 mg/kg on first day then 3 mg/kg daily (every 72 hours in NEONATE up to 2 weeks old, every 48 hours in NEONATE 2 - 4 weeks old)* ***ii) 50 mg daily for 2 - 4 weeks, maximum 6 weeks*** ***iii) 400 mg initially then 200 - 400 mg daily for 6 - 8 weeks.*** *CHILD: 6-12 mg/kg daily (every 72 hours in NEONATE up to 2 weeks old, every 48 hours in NEONATE 2 - 4 weeks old)* *iv) 100 - 200 mg daily* ***v) 50 -** 400 mg daily. CHILD: 3 - 12 mg/kg daily (every 72 hours in NEONATE up to 2 weeks old, every 48 hours in NEONATE 2 - 4 weeks old)*	***i) a) 400 mg on Day 1 followed by 200 mg to 400 mg once daily usually at least 6 to 8 weeks for cryptococcal meningitis.*** ***CHILD ≥4 weeks-11 years:*** ***Treatment: 6-12 mg/kg once daily.*** ***b) 200 mg once daily indefinitely.*** ***CHILD*** ***Maintenance: 6mg/kg once daily*** ***ii) 400 mg on Day 1 followed by 200 mg once daily*** ***CHILD ≥4 weeks-11 years: 6-12 mg/kg once daily.*** ***iii) a) 50 mg to 100 mg once daily for 7 to 14 days*** ***CHILD Loading dose: 6mg/kg on Day 1 followed by 3mg/kg daily.*** ***b) 50 mg once daily for 14 days concurrently with local antiseptic measures to the denture*** ***c) 50 mg to 100 mg once daily for 14 to 30 days.*** ***CHILD*** ***0-14 days Initially, 6 mg/kg, followed by 3 mg/kg every 72 hours.*** ***Max: 12 mg/kg 72 hourly.*** ***15-27 days Initially, 6 mg/kg, followed by 3 mg/kg every 48 hours.*** ***Max: 12 mg/kg 48 hourly.*** ***28 days-11 years Initially, 6 mg/kg, followed by 3 mg/kg once daily.*** ***d) 150 mg once weekly.*** ***iv) a) 150 mg as a single oral dose.*** ***b) 150 mg once-monthly dose may be used for usually 4 to 12 months*** ***c) 150 mg as a single oral dose.*** ***v) 50 mg to 400 mg once daily*** ***vi) a) 150 mg once weekly or 50 mg once daily for normally 2 to 6 weeks*** ***b) 300 mg once weekly for 2 weeks; a third weekly dose of 300-400 mg.*** ***An alternate dosing regimen is 50 mg once daily for 2 to 4 weeks.*** ***Dosing is individualised and according to product insert/protocol.***

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
6.0 NERVOUS SYSTEM			
1.	Lignocaine 4% Solution **Kategori Preskriber:** B **Kaedah Perolehan:** LP	***INDICATION*** ***For anaesthesia of mucous membranes of the oropharyngeal, tracheal and bronchial areas eg. in laryngoscopy and bronchoscopy***	***i) Anaesthesia of mucous membranes*** ***ii) Use for instrumentation of the respiratory and digestive tracts***
		DOSING ***Apply a thick layer under occlusive dressing at least 1 hour before the procedure***	***i) & ii) Dosing is according to product insert/protocol.***
2.	Zolpidem Tartrate 10 mg Tablet **Kategori Preskriber:** A **Kaedah Perolehan:** LP	***DOSING*** ***10-mg tablet daily.*** ***Stilnox should always be taken just before going to bed. In elderly patients or patients with hepatic insufficiency: Dosage should be halved ie, 5 mg. Dosage must never exceed 10 mg/day.***	***ADULT: 10mg daily at bedtime*** ***ELDERLY OR DEBILITATED SUBJECTS: 5mg daily at bed time*** ***Max. dose: 10mg daily***
3.	Zuclopenthixol Acetate 50 mg/ml Injection **Kategori Preskriber:** A* **Kaedah Perolehan:** LP	***INDICATION*** ***Only for treatment of agitated and violent*** *patients suffering from schizophrenia who are not responding to the available standard drugs*	***Initial treatment of acute psychoses, including mania, and exacerbations of chronic psychoses*** *in patients not responding to available standard drugs*
		DOSING ***Clopixol-Acuphase: Clopixol-Acuphase is administered by IM injection. The dosage range should normally be*** *50-150 mg* ***(1-3 mL)*** *IM repeated if necessary, preferably with a time interval of 2-3 days.* ***In a few patients,*** *an additional injection may be needed 24-48 hrs following the 1st injection.* ***In the maintenance therapy, treatment should be continued with oral Clopixol or Clopixol Depot IM after the following guidelines: Change to Oral Clopixol: 2-3 days after the last injection of Clopixol-Acuphase, a patient who has been treated with 100 mg Clopixol-Acuphase, oral treatment should be started at a dosage of about 40 mg daily, possibly in divided dosages. If necessary, the dose can be further increased by 10-20 mg every 2-3 days up to 75 mg or more.***	*50-150mg IM repeated if necessary, preferably within a time interval of 2-3 days. Additional injection may be needed 24-48 hours following the first injection*

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
6.0 NERVOUS SYSTEM			
4.	Zuclopenthixol 20 mg/ml Drops **Kategori Preskriber: A*** **Kaedah Perolehan:** LP	***INDICATION*** *Only for psychoses with insight or compliance*	***i) Acute schizophrenia and other acute psychoses, including agitation*** ***ii) Chronic schizophrenia and other chronic psychoses*** ***iii) Mania***
		DOSAGE ***Acute Schizophrenia and Other Acute Psychoses; Severe Acute States of Agitation; Mania: Oral treatment: Usually*** *10-50 mg/day.* ***In moderate to severe cases initially 20 mg/day increased, if necessary, by 10-20 mg/day every 2-3 days to ≥75 mg daily.***	***i) & iii) 10-50mg daily*** ***Max. dose: 100-150mg daily in 2-3 divided doses*** ***ii) 20-40mg daily***
5.	Zuclopenthixol Decanoate 200 mg/ml Injection **Kategori Preskriber:** B **Kaedah Perolehan:** Kontrak Pusat	***INDICATION*** ***Only for treatment of agitated and violent*** *patients suffering from schizophrenia who are not responding to the available standard drugs*	***Maintenance treatment of schizophrenia and other psychoses, especially with symptoms such as hallucinations, delusions and thought disturbances along with agitation, restlessness, hostility and aggressiveness*** *in patients not responding to available standard drugs*
6.	Sulpiride 200 mg Tablet **Kategori Preskriber**: B **Kaedah Perolehan:** Kontrak Pusat	***INDICATION*** *Acute and chronic schizophrenia, chronic delusional psychoses*	***Acute and chronic psychotic disorders***
		DOSING *200-400 mg twice daily;* ***800 mg daily in predominantly negative symptoms and 2.4 g daily in mainly positive symptoms. Elderly, lower initial dose; increased gradually according to response. Child under 14 years not recommended***	***200-1000mg daily***
7.	Cinnarizine 25 mg Tablet **Kategori Preskriber:** B **Kaedah Perolehan:** APPL	***INDICATION*** *Vestibular disorders*	*i) Vestibular disorders* ***ii) Motion sickness***
		DOSING ***Adult: One tablet 3 times daily***	***i) ADULT and CHILD> 12 years*** ***25mg three times a day*** ***ii) 25mg 2 hours before travel and 12.5mg every 8 hours during journey*** ***CHILD 5-12 years: Half the adult dose*** ***Dosing is according to product insert.***

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
6.0 NERVOUS SYSTEM			
8.	Memantine HCl 10 mg Tablet **Kategori Preskriber:** A* **Kaedah Perolehan:** Kontrak Pusat	***INDICATION*** *As monotherapy or as adjunctive therapy with cholinesterase inhibitors for the symptomatic treatment of patients with moderate to severe Alzheimer's disease.*	***Treatment of moderate to severe Alzheimer's disease.***
9.	Memantine HCl 20 mg Tablet **Kategori Preskriber:** A* **Kaedah Perolehan:** LP		
8a. 9a.	Memantine HCl 10 mg Tablet Memantine HCl 20 mg Tablet	***DOSING*** ***Adult Initially*** *5 mg/day on the 1st week, 5mg twice a day on the 2nd week, then 15 mg/day* ***(10mg in the morning and 5mg in the evening)*** *on the 3rd week.* ***From the*** *4th week on,* ***continue treatment with maintenance dose of*** *20 mg/day* ***(10mg twice a day).*** *Max: 20 mg/day.*	***Initial*** ***Week 1: 5mg daily*** ***Week 2: 10mg daily*** ***Week 3: 15mg daily*** ***Week 4 and subsequent: 20mg daily*** ***Maintenance*** ***20mg daily*** ***Max. dose: 20mg daily***
10.	Chlorpromazine HCl 25 mg Tablet **Kategori Preskriber:** B **Kaedah Perolehan:** APPL	***INDICATION*** *Psychosis mania and agitation*	***i) Psychotic conditions*** ***ii) Anti-emetic***
11.	Chlorpromazine HCl 100 mg Tablet **Kategori Preskriber:** B **Kaedah Perolehan:** APPL		
10a. 11a.	Chlorpromazine HCl 25 mg Tablet Chlorpromazine HCl 100 mg Tablet	***DOSING*** *ADULT: Initial dose - 25 mg 3 times daily* ***according to response up to 1 g daily. PAEDIATRIC: Up to 5 years: 0.5 mg/kg body weight every 4 - 6 hours (Maximum 40 mg daily). CHILD 6 - 12 years: A third to half adult dose (Maximum 75 mg daily)***	***ADULT:*** ***Initial: 25-50mg two- three times daily*** ***Maintenance: 25-100mg two- three times daily*** ***CHILD: Not recommended*** ***Dosing is according to product insert/ protocol.***

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
6.0 NERVOUS SYSTEM			
12.	Phenytoin Sodium 125 mg/5ml Suspension **Kategori Preskriber:** B **Kaedah Perolehan:** LP	***INDICATION*** ***Epilepsy***	***Control of tonic-clonic (grand mal) and psychomotor seizures.***
		DOSING *ADULT: Patients with no previous treatment may be started on 1 teaspoonful or 5 mL (125 milligrams) 3 times daily. It is then individualized to the patient. An increase to 5 teaspoonfuls (625 milligrams) may be made if necessary.* *CHILD: Initially 5 mg/kg/day in 2 - 3 divided doses. Maintenance: 4 - 8 mg/kg/day. Maximum: 300 mg/day.* ***Children over 6 years and adolescents may require the minimum adult dose (300mg/day).***	*ADULT:* *Initial: 125mg* ***2-****3 times daily. Max. dose: 625mg daily* *CHILD:* *Initial: 5mg/kg/day in 2-3 divided doses* *Maintenance: 4-8 mg/kg/day in equally divided doses* *Max. dose: 300mg daily* ***Dosing is according to product insert.***
13.	Phenytoin Sodium 30 mg Capsule **Kategori Preskriber:** B **Kaedah Perolehan:** APPL	***INDICATION*** *Epilepsy*	***Control of tonic-clonic (grand mal) and psychomotor seizures.***
14.	Phenytoin Sodium 100 mg Capsule **Kategori Preskriber:** B **Kaedah Perolehan:** APPL		
13a. 14a.	Phenytoin Sodium 30mg Capsule Phenytoin Sodium 100 mg Capsule	***DOSING*** *ADULT and CHILD more than 6 years: 300-400 mg/day in 3 - 4 divided doses before meals. Maximum: 600 mg/day.* *CHILD: Initially 5 mg/kg/day in 2 - 3 divided doses. Maintenance: 4 - 8 mg/kg/day. Maximum: 300 mg/day*	***ADULT*** ***Initial: 300mg daily in 3 equally divided doses*** ***Maintenance: 300-400 daily in 3-4 equally divided doses*** ***Max. dose: 600mg daily*** ***CHILD*** ***Initial: 5mg/kg/day in 2-3 equally divided doses*** ***Maintenance: 4-8mg/kg/day*** ***Max. dose: 300mg daily*** ***Dosing is according to product insert.***

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
6.0 NERVOUS SYSTEM			
15.	Phenytoin Sodium 50mg/ml Injection **Kategori Preskriber:** B **Kaedah Perolehan:** APPL	***INDICATION*** ***Status epilepticus***	***i) Control of status epilepticus of the tonic-clonic (grand mal) type*** ***ii) Prevention and treatment of seizures occurring during or following neurosurgery.***
		DOSING *i) Status epilepticus: ADULT 10 - 15 mg/kg by slow IV. Maximum 50 mg/minute. Maintenance: 100 mg orally/IV every 6 - 8 hours. CHILD 15 - 20 mg/kg by slow IV. Maximum: 1 - 3 mg/kg/minute* *ii) Neurosurgery 100 - 200 mg IM approximately at 4 hourly interval*	*i) ADULT* ***Loading: 10****-15mg/kg slow IV (max. 50mg per minute)* *Maintenance: 100mg orally or IV every 6-8 hours* ***NEONATE &*** *CHILD* ***Loading:*** *15-20mg/kg IV slow IV (max. 1-3mg/kg/minute)* *ii) 100-200mg deep IM at approximately 4 hour intervals* ***during surgery and continued postoperative.*** ***Dosing is individualised and according to product insert / protocol.***
16.	Benzhexol 2 mg Tablet **Kategori Preskriber:** B **Kaedah Perolehan:** APPL	***INDICATION*** ***i) Parkinson's disease*** ***ii) Drug induced parkinsonism*** ***iii) Dystonias***	***i) Symptomatic treatment of paralysis agitans and of parkinsonism, arteriosclerotic, idiopathic, or post-encephalitic origin*** ***ii) Alleviate extrapyramidal syndrome induced by phenothiazine derivatives or reserpine*** ***iii) Spasmodic torticollis, facial spasms and other dyskinesia***
		DOSING *ADULT: Initially 1 mg daily, increase gradually.* *Maintenance: 5 - 15 mg daily in 3 - 4 divided doses. (Max 15mg/day)*	***i) & iii)*** ***Initial: 1-2mg daily*** ***Maintenance: Gradual increment to 6-10mg daily according to response*** ***ii) 5-15mg daily*** ***Dosing is individualised and according to product insert / protocol.***

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
6.0 NERVOUS SYSTEM			
17.	Rivastigmine 4.6mg/24hr Transdermal Patch **Kategori Preskriber:** A* **Kaedah Perolehan:** LP	***INDICATION*** *Mild to moderately severe dementia associated with Alzheimer's or Parkinson's disease*	*i) Mild to moderately severe dementia of the Alzheimer's type* ***ii) Severe dementia of the Alzheimer's type*** *iii) Mild to moderately severe dementia associated with Parkinson's disease*
18.	Rivastigmine 9.5 mg/24hr Transdermal Patch **Kategori Preskriber:** A* **Kaedah Perolehan:** LP		
19.	Rivastigmine 13.3mg/24hr Transdermal Patch **Kategori Preskriber:** A* **Kaedah Perolehan:** LP	***INDICATION*** *i) Alzheimer's type: Mild, moderately severe or severe dementia* *ii) Mild to moderately severe dementia associated with Parkinson's disease.*	
17a. 18a. 19a.	Rivastigmine 4.6mg/24hr Transdermal Patch Rivastigmine 9.5 mg/24hr Transdermal Patch Rivastigmine 13.3mg/24hr Transdermal Patch	***DOSING*** *4.6mg/24hr & 9.5mg/24hr* *Initial, 4.6 mg/24 hr patch TOPICALLY once daily; after a minimum of 4 weeks and good tolerability, increase the dose to 9.5 mg/24 hour patch once daily* *13.3mg/24hr* *Initial, 4.6mg/24 hours patch once daily, after a minimum of 4 weeks of treatment and if well tolerated, increase to 9.5mg/24 hours or 13.3mg/24 hours* ***(individual responses to rivastigmine may vary and some patients may derive additional benefit from higher doses)***	***Initial: 4.6mg/24hr once daily*** ***Maintenance: 9.5mg/24hr once daily after a minimum of 4 weeks and then 13.3mg/24hr if tolerated*** ***Dosing is individualised and according to product insert.***
17b. 18b. 19b.	Rivastigmine 4.6mg/24hr Transdermal Patch Rivastigmine 9.5 mg/24hr Transdermal Patch Rivastigmine 13.3mg/24hr Transdermal Patch	***PRESCRIBING RESTRICTIONS*** ***4.6mg/24hr & 9.5mg/24hr*** ***NIL*** ***13.3mg/24hr*** *Use as second line/alternative option if the first line medication with oral tablet failed or patients are not able to tolerate the oral medication*	***4.6mg/24hr & 9.5mg/24hr*** ***Use as second line/alternative option if the first line medication with oral tablet failed or patients are not able to tolerate the oral medication***

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
7.0 CARDIOVASCULAR SYSTEM			
1.	Amiodarone 50 mg/ml Injection **Kategori Preskriber:** A* **Kaedah Perolehan:** LP	***INDICATION*** *Arrhythmias when other drugs are contraindicated or ineffective*	***i) Arrhythmias*** ***ii) Cardiopulmonary resuscitation of shock-resistant ventricular fibrillation in cardiac arrest***
		DOSING *Initial infusion of 5mg/kg via large venous access over 20-120 minutes* ***with ECG monitoring; subsequent infusion given if necessary according to response up to a*** *maximum of 1.2 g in 24 hours*	***i) Initial: 5mg/kg over 20-120minutes*** ***Maintenance: 10-20mg/kg/24hr*** ***Max. dose: 1.2g/24hr*** ***ii) Initial: 300mg or 5mg/kg rapid*** ***Additional 150mg if condition persists.*** ***Dosing is according to product insert/ protocol.***
2.	Amiodarone 200 mg Tablet **Kategori Preskriber:** A* **Kaedah Perolehan:** LP	***INDICATION*** *Arrhythmias*	*Arrhythmias*
		DOSING *200 mg 3 times daily for 1 week, then reduced to 200 mg twice daily for another week.* *Maintenance dose, usually 200 mg daily or the minimum required to control the arrhythmia*	*200 mg 3 times daily for 1 week, then reduced to 200 mg twice daily for another week.* *Maintenance dose, usually 200 mg daily or the minimum required to control the arrhythmia* ***Dosing is according to product insert/ protocol.***
3.	Glyceryl Trinitrate Aerosol Spray 400mcg (metered dose) **Kategori Preskriber:** B **Kaedah Perolehan:** LP	***INDICATION*** *Prophylaxis and treatment of angina and* ***left ventricular failure***	*i) Angina* ***pectoris*** ***ii) Variant angina***
		DOSING ***At the onset of an attack, one or two metered sprays should be administered on or under the tongue. A spray maybe repeated approximately every 5 minutes as needed. No more than 3 metered sprays are recommended within 15 minute period. If chest pain persists after a total of 3 sprays, prompt medical attention is recommended. Aerosol may be used prophylactically 5 to 10 minutes before engaging in activities that might precipitate an acute attack***	***1-2 metered sprays sublingual every 5 minutes as required or 5-10minutes prior to activities that might precipitate an acute attack.*** ***Dosing is according to product insert or protocol.***

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
7.0 CARDIOVASCULAR SYSTEM			
4.	Glyceryl Trinitrate 5 mg/ml Injection **Kategori Preskriber:** A **Kaedah Perolehan:** APPL	***INDICATION*** *i) **Prophylaxis and treatment of** angina, **left ventricular failure.*** *ii) Congestive heart failure* *ii) Control of hypertensive episodes*	*i) Angina **pectoris*** *ii) Congestive heart failure* *ii) Control of hypertensive episodes* ***iv) Production of controlled hypotension during surgery***
		DOSING *Initial of 10-25mcg/min* *Dosing is according to product insert.*	*Initial* ***5-**25mcg/min* *Dosing is **individualised** and according to product insert **or protocol.***
5.	Isosorbide-5-Mononitrate 60 mg SR Tablet **Kategori Preskriber:** A **Kaedah Perolehan:** LP	***INDICATION*** ***Prophylaxis and treatment of** angina pectoris*	***Angina pectoris***
		DOSING ***60mg once daily, increase to 120 mg daily***	***Initial: 30mg daily*** ***Maintenance: 30-60mg once daily*** ***Max. 120mg once daily***
6.	Isosorbide Dinitrate 1 mg/ml Injection **Kategori Preskriber:** A **Kaedah Perolehan:** LP	***DOSING*** *2-**10** mg/hour IV infusion after dilution, **higher doses up to 20 mg/hour may be required***	*2-**12**mg IV per hour after dilution* ***Dosing is according to product insert or protocol.***
7.	Bosentan 125 mg tablet **Kategori Preskriber:** A* **Kaedah Perolehan:** LP	***INDICATION*** *For the treatment of pulmonary arterial hypertension (PAH) in patients with WHO Class **III or IV symptoms, to improve exercise ability and decrease the rate of clinical worsening*** ***(To be used by those who are trained and specialized in treating and managing PAH)***	*Treatment of pulmonary arterial hypertension (PAH) in patients of WHO functional class **II-IV**.*
8.	Frusemide 40 mg Tablet **Kategori Preskriber:** B **Kaedah Perolehan:** APPL	***INDIKASI*** ***Pulmonary** oedema*	***Oedema***
9.	Frusemide 10mg/ml oral solution **Kategori Preskriber:** B **Kaedah Perolehan:** LP		

Bil.	Nama Generik/ Kategori Preskriber/ Kaedah Perolehan	Indikasi / Dos dalam FUKKM	Indikasi/Dos Baru
7.0 CARDIOVASCULAR SYSTEM			
8a. 9a.	Frusemide 40 mg Tablet Frusemide 10mg/ml oral solution	***DOSING*** *TABLET* *ADULT: Initial 40 - 80 mg* ***on morning if required, can be increased to a max of 1 g/day in certain cases especially in chronic renal failure.*** *CHILD: 1 - 3 mg/kg daily* *ORAL SOLUTION* *ADULT:* ***The usual initial oral dose is*** *40mg once daily, adjusted as necessary* ***according to response.*** ***Mild cases may respond to 20mg daily or 40mg on alternate days. Some patients may need doses of 80mg or more daily given as one or two doses daily; or intermittently. Severe cases may require gradual titration of the frusemide dosage up to 600mg daily.*** *CHILDREN:* ***The usual dose is*** *1 to 3mg/kg daily up to a maximum dose of 40mg daily.*	***ADULT*** ***Initial: 20-80mg daily*** ***Max. 600mg/day*** ***CHILD*** ***1-3mg/kg daily*** ***Max. 40mg/day*** ***Dosing is individualised and according to product insert / protocol.***
10.	Frusemide 10 mg/ml Injection **Kategori Preskriber**: B **Kaedah Perolehan:** APPL	***INDICATION*** ***Pulmonary*** *oedema*	***Oedema***
		DOSING ***Initially*** *20 -40 mg IM or slow IV* ***(rate not exceeding 4 mg/min).*** *CHILD: 0.5 - 1.5 mg/kg.* ***Max: 20 mg daily***	***Initial****: 20-50mg* ***once via*** *slow IV or IM* ***Maintenance: Increase by 20mg every 2 hours and titrate to an effective dose if necessary*** *CHILD: 0.5 - 1.5 mg/kg* ***6-24hourly.*** ***Dosing is individualised and according to product insert / protocol.***
11.	Lignocaine, Aluminium Acetate, Zinc Oxide and Hydrocortisone Suppository **Kategori Preskriber:** B **Kaedah Perolehan:** APPL	***INDICATION*** *Anorectal pain, pruritis, inflammation and irritation*	***Treatment of pain, itching and discomfort arising from irritated anorectal issues***
		DOSING *1 suppository to be used once or twice daily.* ***Not for prolonged use.***	*1 suppository once or twice daily* ***and as required after each bowel action. Max: 5 suppositories/day.***

Nota:
LP: *Local Purchase* (Pembelian Tempatan
APPL: *Approved Product Purchase List*