KEMENTERIAN KESIHATAN MALAYSIA
(Ministry of Health Malaysia)
Pejabat Pengarah Kanan Perkhidmatan Farmasi
(Office of the Senior Director of Pharmaceutical Services)
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MALAYSIA

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Ruj. Kami : KKM.600-34/4/04 Jld. 2 (46)
Tarikh : 17 Disember 2019

SEPERTI SENARAI EDARAN

YBhg. Datuk/Dato' Seri/ Dato'/Datin/Tuan/Puan,

PEKELILING PINDAAN/TAMBAHAN KEPADA FORMULARI UBAT-UBATAN KEMENTERIAN KESIHATAN MALAYSIA BIL. 3/2019

Saya dengan segala hormatnya merujuk kepada perkara di atas.

2. Sukacita dimaklumkan bahawa Mesyuarat Panel Kaji Semula Senarai Ubat-ubatan KKM Bil. 3/2019 yang diadakan pada 27 November 2019 telah mempertimbangkan permohonan-permohonan pindaan/tambahan kepada Formulari Ubat KKM (FUKKM). Keputusan pindaan/ tambahan yang telah diluluskan adalah seperti di **Lampiran A1** (penyenaraian ubat baru) dan **Lampiran A2** (penambahan indikasi ubat). Penggunaan ubat-ubatan yang terdapat dalam FUKKM perlu dipantau dan sebarang kesan advers hendaklah dilaporkan kepada Jawatankuasa Penasihat Kesan Advers Ubat Kebangsaan (MADRAC) di Bahagian Regulatori Farmasi Negara (NPRA).

3. Selain itu, harga ubat yang terdapat dalam senarai di lampiran merupakan harga yang diisytiharkan oleh pihak syarikat semasa permohonan pindaan/tambahan kepada FUKKM dikemukakan kepada Bahagian ini. Sebarang perbezaan harga (melebihi harga yang ditawarkan) di peringkat hospital/ institusi KKM hendaklah dilaporkan kepada Cawangan Pengurusan Harga Ubat, Bahagian Amalan dan Perkembangan Farmasi, berserta dokumen sokongan berkaitan supaya tindakan selanjutnya dapat diambil.

4. Sehubungan dengan itu, mohon kerjasama YBhg. Datuk/Dato' Seri/ Dato'/Datin/Tuan/Puan untuk memanjangkan maklumat ini kepada fasiliti yang berkaitan di negeri atau jabatan masing-masing.

Perhatian YBhg. Datuk/Dato' Seri/ Dato'/Datin/Tuan/Puan dalam perkara ini amatlah dihargai.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR. RAMLI BIN ZAINAL) RPh. 1045
Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia.

RH/rr/nar

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s.k.

1. **Ketua Setiausaha**
   Kementerian Kesihatan Malaysia

2. **Ketua Pengarah Kesihatan**
   Kementerian Kesihatan Malaysia

3. **Pengarah Kanan (Kesihatan Pergigian)**
   Kementerian Kesihatan Malaysia

4. **Pengarah**
   Bahagian Perkembangan Perubatan
   Kementerian Kesihatan Malaysia

5. **Pengarah**
   Bahagian Pembangunan Kesihatan Keluarga
   Kementerian Kesihatan Malaysia

6. **Pengarah**
   Bahagian Kawalan Penyakit
   Kementerian Kesihatan Malaysia

7. **Pengarah**
   Bahagian Regulatori Farmasi Negara
   Kementerian Kesihatan Malaysia

8. **Pengarah**
   Bahagian Dasar dan Perancangan Strategik Farmasi
   Kementerian Kesihatan Malaysia

9. **Pengarah**
   Bahagian Amalan & Perkembangan Farmasi
   Kementerian Kesihatan Malaysia

10. **Pengarah Kesihatan Negeri**
    Johor/ Kedah/ Kelantan/ Melaka/ Negeri Sembilan/ Pahang/ Perak/ Pulau Pinang/ Perlis/ Sabah/ Sarawak/ Selangor/ Terengganu/ Wilayah Persekutuan Kuala Lumpur dan Putrajaya/ Wilayah Persekutuan Labuan

11. **Setiausaha Bahagian (Perolehan & Penswastaan)**
    Kementerian Kesihatan Malaysia

12. **Semua Ahli Panel Kaji Semula Senarai Ubat-ubatan**
Kementerian Kesihatan Malaysia

13. **Semua Pengerusi JK Kerja Ubat-ubatan**
Kementerian Kesihatan Malaysia

14. **Timbalan Pengarah (Teknologi Maklumat & Informatik Farmasi)**
Bahagian Dasar dan Perancangan Strategik Farmasi
(bagi tujuan pengemaskinian sistem PhIS).

15. **Ketua Penolong Pengarah Kanan**
Sektor Farmasi Kesihatan Awam
Bahagian Perkembangan Kesihatan Awam
Kementerian Kesihatan Malaysia

16. **Ketua Pustakawan**
Kementerian Kesihatan Malaysia

17. **Unit Teknikal Bantuan Perubatan**
Pejabat Timbalan Ketua Pengarah Kesihatan (Perubatan)
Kementerian Kesihatan Malaysia

18. **Ketua Jabatan Farmasi**
Hospital Canselor Tuanku Mukhriz
Pusat Perubatan Universiti Kebangsaan Malaysia

19. **Ketua Pegawai Farmasi**
Pusat Perubatan Universiti Malaya

20. **Ketua Pegawai Farmasi**
Hospital Universiti Sains Malaysia

21. **Ketua Pegawai Farmasi**
Pusat Perubatan Universiti Islam Antarabangsa Malaysia (PPUIAM)

22. **Pegawai Farmasi**
Institut Jantung Negara

SENARAI EDARAN

1. **Timbalan Pengarah Kesihatan Negeri (Farmasi)**
   Johor/ Kedah/ Kelantan/ Melaka/ Negeri Sembilan/ Pahang/ Perak/ Pulau Pinang/ Perlis/ Sabah/ Sarawak/ Selangor/ Terengganu/ Wilayah Persekutuan Kuala Lumpur dan Putrajaya/ Wilayah Persekutuan Labuan

2. **Ketua Jabatan Farmasi**
   Hospital Kuala Lumpur

3. **Ketua Jabatan Farmasi**
   Institut Kanser Negara

4. **Ketua Jabatan Farmasi**
   Hospital Wanita dan Kanak-kanak Kuala Lumpur

5. **Pegawai Farmasi y/m**
   Institut Perubatan Respiratori.

6. **Pegawai Farmasi y/m**
   Pusat Darah Negara

PINDAAN / TAMBAHAN KEPADA FORMULARI UBAT KKM (FUKKM) BIL. 3/2019

PERMOHONAN PINDAAN/TAMBAHAN KEPADA FUKKM YANG DILULUSKAN

BIL.	NAMA UBAT	PINDAAN	LAMPIRAN
1.	Ceftolozane 1000mg & Tazobactam 500mg *Injection*	Penyenaraian Ubat Baru	A1
2.	Afatinib Dimaleate 30mg & 40mg *Film-Coated Tablet*		
3.	Nintedanib 100mg & 150 mg *Capsule*		
4.	Zoledronic Acid 4mg *Injection*	Tambahan Indikasi	A2

LAMPIRAN A1

UBAT-UBATAN BARU YANG DILULUSKAN UNTUK DISENARAIKAN DALAM FUKKM

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
1.	Ceftolozane 1000mg & Tazobactam 500mg *Injection* MDC: J01DI54-000-P40-01-001 *Cost/unit (RM):* *RM265.95 / vial* *Prescriber Category:* *A** *(Infectious Disease Consultant/ Specialists)*	*Approved Indication(s):* *For the treatment of patients 18 years or older with the following infections.* *i) Treatment of complicated Intra-abdominal Infections (cIAI), to be used in combination with metronidazole.* *ii) Treatment of complicated Urinary Tract Infections (cUTI) including Pyelonephritis* *Prescribing restriction:* *Confirmed carbapenem-resistant Pseudomonas aeruginosa as an alternative to Polymyxins (Polymyxin sparing).* *Dose:* *1.5g (ceftolozane 1g and tazobactam 0.5g) administered every 8 hours by intravenous infusion over 1 hour in patients 18 years or older with normal renal function or mild renal impairment.* *i) 1.5g every 8 hourly for 4-14 days* *ii) 1.5g every 8 hourly for 7 days* *Precaution(s):* *Decreased efficacy in patients with baseline creatinine clearance of 30 to ≤50 mL/min, hypersensitivity reactions, Clostridium difficile-associated diarrhea, development of drug-resistant bacteria.* *Adverse reaction(s):* *Nausea, headache, diarrhoea, pyrexia, constipation, insomnia, vomiting, hypokalaemia, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), anaemia, thrombocytosis, abdominal pain, anxiety, dizziness, hypotension, atrial fibrillation, rash, reaction at the infusion site.* *Contraindication(s):* *Hypersensitivity to the active substances or any of the active excipients or cephalosporin antibacterial agent. Severe hypersensitivity (e.g. anaphylactic reaction, severe skin reaction) to any other type of beta-lactam antibacterial agent (e.g. penicillins or carbapenems).* *Interaction(s):* *Ceftolozane & tazobactam is unlikely to cause clinically relevant drug-drug interactions related to cytochromes and transporters at therapeutic concentrations.*

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
2.	Afatinib Dimaleate 30mg & 40mg *Film-Coated Tablet* MDC: 30mg: L01XE13-253-T32-02-001 40mg: L01XE13-253-T32-03-001 *Cost/unit (RM):* RM 50.00/ tablet *Prescriber Category:* *A** *(Consultant/Specialists from disciplines of oncology and oncology-trained respiratory physician)*	*Approved Indication(s):* *First-line monotherapy for the treatment of Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s).* *Prescribing restriction(s):* *i) Adenocarcinoma histology.* *ii) Patient's ECOG Performance Status 0-1.* *Dose:* *40mg once daily to be taken without food. Maximum dose is 50mg once daily.* *Precaution(s):* *False results of EGFR mutation status assessment; patients with risk factors of diarrhoea (female, lower body weight & underlying renal impairment); patients with an acute onset and/or unexplained worsening of pulmonary symptoms (dyspnoea, cough, fever); severe hepatic impairment; keratitis; left ventricular function; patient's fertility status, pregnancy and lactation.* *Adverse reaction(s):* *Paronychia; decreased appetite; epistaxis; diarrhoea, stomatitis, nausea, vomiting; rash, dermatitis acneiform, pruritus, dry skin; cystitis; dehydration, hypokalaemia; dysgeusia; conjunctivitis, dry eye; rhinorrhoea; dyspepsia, cheilitis; increased alanine aminotransferase or aspartate aminotransferase; Palmar-plantar erythrodysesthesia syndrome; nail disorders; muscle spasms; renal impairment/renal failure; pyrexia; decreased weight.* *Contraindication(s):* *Hypersensitivity to Afatinib or to any of the excipients.* *Interaction(s):* *Strong P-gp inhibitors (e.g. ritonavir, cyclosporine A, ketoconazole, itraconazole, erythromycin, verapamil, quinidine, tacrolimus, nelfinavir, saquinavir, and amiodarone) may increase exposure of afatinib; strong P-gp inducer (e.g. rifampicin, carbamazepine, phenytoin, phenobarbital or St. John's wort) may decrease afatinib exposure; high-fat meal.*

BIL.	MAKLUMAT UBAT	KETERANGAN UBAT
3.	Nintedanib 100mg & 150mg *Capsule* MDC: 100mg: L01XE31-189-C40-01-001 150mg: L01XE31-189-C40-02-001 *Cost/unit (RM):* *RM 58.33/capsule* *(for both strengths)* *Prescriber Category:* *A** *(Consultant/Specialists from discipline of Respiratory only [Pulmonologist])*	*Approved Indication(s):* *For the treatment of Idiopathic Pulmonary Fibrosis (IPF) in adults* *Prescribing restriction:* *None* *Dose:* *The recommended dose is 150 mg twice daily administered approximately 12 hours apart.* *The 100 mg twice daily dose is only recommended to be used in patients who do not tolerate the 150 mg twice daily dose.* *Precaution(s):* *Gastrointestinal disorders; moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment; patients at known risk for bleeding; patients at higher cardiovascular risk including known coronary artery disease, hypertension, acute myocardial ischemia, thromboembolic events, QTc prolongation; co-administration with pirfenidone, gastrointestinal perforations.* *Adverse reaction(s):* *Diarrhoea, nausea, abdominal pain, increased hepatic enzyme, weight decreased, appetite decreased, bleeding, vomiting, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased gamma glutamyl transferase (GGT).* *Contraindication(s):* *Hypersensitivity to nintedanib, to peanut or soya, or to any of the excipients.* *Interaction(s):* *Co-administration of nintedanib with potent P-gp inhibitors (e.g. ketoconazole, erythromycin or cyclosporine) may increase exposure to nintedanib. Potent P-gp inducers (e.g. rifampicin, carbamazepine, phenytoin, and St. John's Wort) may decrease exposure to nintedanib.*

LAMPIRAN A2

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

BIL	UBAT DALAM FUKKM	PINDAAN	KETERANGAN UBAT
1.	Zoledronic Acid 4mg *Injection*	*Approved to add indication(s):* *Prevention of skeletal related events (SREs) for metastatic cancers of solid tumours* *Prescribing Restriction(s):* *-* *Cost/unit (RM):* *RM93.50/vial* *Gov. Contract (exp. 8th Sep 2021)* *Prescriber Category:* *A** *(Consultant/ Specialists from discipline of Oncology only)*	*Dose:* *4mg reconstituted and should be given as a 15-minute IV infusion* ***every 12 weeks*** *(as advised in MaHTAS 2018 Report)* *Precaution(s):* *Inadequate hydration, concomitant administration with other bisphosphonates, deterioration of renal function, severe renal impairment (not recommended), severe hepatic impairment, atypical fractures of the femur, musculoskeletal pain, osteonecrosis, concomitant administration with other hypocalcaemia causing drugs.* *Adverse reaction(s):* *Aneamia, headache, paraesthesia, sleep disorder, conjunctivitis, nausea, vomiting, decreased appetite, hyperhidrosis, bone pain, myalgia, arthralgia, generalized body pain, joint stiffness, hypertension, renal impairment, acute phase reaction, pyrexia, influenza-like illness (including: fatigue, chills, malaise, and flushing), peripheral oedema, asthenia, hypophosphataemia, blood creatinine and blood urea increased, hypocalcaemia.* *Contraindication(s):* *Hypersensitivity to zoledronic acid or other bisphosphonates, pregnancy, lactation* *Interaction(s):* *Aminoglycosides, calcitonin, loop diuretics, other potentially nephrotoxic drugs, anti-angiogenic drugs*