Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Tagrisso Film-Coated Tablet 40mg [Osimertinib 40mg] Tagrisso Film-Coated Tablet 80mg [Osimertinib 80mg]	**INDICATION :** TAGRISSO as monotherapy is indicated for: • the treatment of adult patients with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy. **POSOLOGY :** When considering the use of TAGRISSO, EGFR mutation status should be determined using a validated test method (see section 4.4) for: • exon 19 deletions or exon 21 (L858R) substitution mutations (in tumour specimens for adjuvant treatment or for treatment of locally advanced, unresectable tumours and tumour or plasma specimens for first-line treatment). <u>Posology</u> Monotherapy The recommended dose is 80 mg osimertinib once a day. <u>Dose adjustments</u> Dose reduction guidelines for adverse reactions toxicities are provided in Table 1. **Table 1. Recommended dose modifications for TAGRISSO**	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>Target organ</th><th>Adverse reaction[a]</th><th>Dose modification</th></tr>
<tr><td rowspan="4">Pulmonary[b]</td><td>ILD/Pneumonitis[c]</td><td>Permanently discontinue TAGRISSO</td></tr>
<tr><td>Grade 1 Radiation Pneumonitis</td><td>Consider withholding or continue TAGRISSO, as clinically indicated</td></tr>
<tr><td>Grade 2 Radiation Pneumonitis</td><td>Withhold TAGRISSO until symptoms resolve. TAGRISSO may be restarted. Permanently discontinue if symptoms do not resolve after 4 weeks or Grade 2 Radiation Pneumonitis recurs</td></tr>
<tr><td>Grade 3 or 4 Radiation Pneumonitis</td><td>Permanently discontinue TAGRISSO</td></tr>
</table>
[a] Note: The intensity of clinical adverse events graded by the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

[b] Refer to section 4.4.

[c] ILD/Pneumonitis including ILD/Pneumonitis following definitive platinum-based chemoradiation therapy.

ECGs: Electrocardiograms; QTc: QT interval corrected for heart rate
</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Scemblix 20mg film-coated tablet [Asciminib 20mg (corresponds to Asciminib hydrochloride 21.62mg)] Scemblix 40mg film-coated tablet [Asciminib 40mg (corresponds to Asciminib hydrochloride 43.24mg)]	**INDICATION :** SCEMBLIX is indicated for the treatment of adult patients with: ● Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). ● Previously treated Ph+ CML in CP. **POSOLOGY :** **2.1 Recommended Dosage in Patients with Newly Dlagnosed or Previously Treated Ph+CML-CP** The recommended dose of SCEMBLIX is 80 mg taken orally once daily at approximately the same time each day or 40 mg orally twice daily at approximately 12-hour intervals. The recommended dose of SCEMBLIX is taken orally without food. Avoid food consumption for at least 2 hours before and 1 hour after taking SCEMBLIX [see Clinical Pharmacology (12.2)]. Continue treatment with SCEMBLIX as long as clinical benefit is observed or until unacceptable toxicity occurs. **2.3 Missed Dose** <u>Once Daily Dosage Regimen:</u> If a SCEMBLIX dose is missed by more than approximately 12 hours, skip the dose and take the next dose as scheduled. <u>Twice Daily Dosage Regimens:</u> If a SCEMBLIX dose is missed by more than approximately 6 hours, skip the dose and take the next dose as scheduled.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

<table>
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<tr><td></td><td></td><td>
2.4 Dosage Modifications

<u>Dosage Modifications for Patients with Newly Diagnosed or Previously Treated Ph+ CML-CP</u>
For the management of adverse reactions, reduce the SCEMBLIX dose as described in Table 1.

Table 1: Recommended Dosage Reductions for SCEMBLIX for Adverse Reactions
<table>
<tr><th>Dosage reduction</th><th>Dosage for Patients with newly diagnosed or previously treated Ph+ CML-CP</th><th>Dosage for patients with Ph+ CML-CP with the T315I mutation</th></tr>
<tr><td>First</td><td>• 40 mg once daily
OR
• 20 mg twice daily</td><td>160 mg twice daily</td></tr>
<tr><td>Subsequent reduction</td><td>Permanently discontinue SCEMBLIX in patients unable to tolerate 40 mg once daily OR 20 mg twice daily.</td><td>Permanently discontinue SCEMBLIX in patients unable to tolerate 160 mg twice daily.</td></tr>
</table>
</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Rafinlar 50mg Hard Capsule [Dabrafenib mesylate 59.25 mg (equivalent to Dabrafenib 50mg)] Rafinlar 75mg Hard Capsule [Dabrafenib mesylate 88.88 mg (equivalent to Dabrafenib 75mg)]	**INDICATION :** <u>BRAF V600E Mutation-Positive Metastatic NSCLC</u> RAFINLAR is indicated, in combination with trametinib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation. **POSOLOGY :** <u>Patient Selection</u> NSCLC • Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with RAFINLAR and trametinib. <u>Recommended Dosage</u> Adult Patients The recommended dosage for RAFINLAR capsules in adult patients, either used as monotherapy or in combination with trametinib, is 150 mg (two 75mg capsules) twice daily (corresponding to a total daily dose of 300mg). The recommended dose of trametinib, when used in combination with dabrafenib, is 2 mg once daily. <u>Duration of treatment</u> • The recommended duration of treatment for patients with unresectable or metastatic melanoma, solid tumors or metastatic NSCLC is until disease progression or unacceptable toxicity.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Meqsel 0.5mg Film-Coated Tablet [Trametinib dimethyl sulfoxide equivalent to 0.5 mg of trametinib] Meqsel 2mg Film-Coated Tablet [Trametinib dimethyl sulfoxide equivalent to 2mg of trametinib]	**INDICATION :** <u>BRAF V600E Mutation-Positive Metastatic NSCLC</u> MEQSEL is indicated, in combination with dabrafenib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation. **POSOLOGY :** <u>Patient Selection</u> NSCLC • Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with MEQSEL and dabrafenib. <u>Recommended Dosage</u> Adult Patients The recommended dosage for MEQSEL tablets in adult patients, either used as monotherapy or in combination with dabrafenib, is 2 mg once daily. The recommended dose of dabrafenib, when used in combination with trametinib, is 150 mg twice daily. <u>Duration of treatment</u> • The recommended duration of treatment for patients with unresectable or metastatic melanoma, solid tumors or metastatic NSCLC is until disease progression or unacceptable toxicity.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	MMR II VACCINE [Live Attenuated Measles, Rubella and Mumps Virus]	**INDICATION (*POSOLOGY*) :** FOR **INTRAMUSCULAR** OR SUBCUTANEOUS ADMINISTRATION **ONLY** Do not inject intravenously. Do not give immune globulin (IG) concurrently with M-M-R II. The dose for any age is **approximately** 0.5 mL administered **intramuscularly** or subcutaneously, preferably into the outer aspect of the upper arm. CAUTION: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. To reconstitute, use only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug. M-M-R II, when reconstituted, is clear yellow. RECOMMENDED VACCINATION SCHEDULE Individuals first vaccinated at 12 months of age or older should be revaccinated at 4-6 years of age or 11-12 years of age. Revaccination is intended to seroconvert those who do not respond to the first dose. MEASLES OUTBREAK SCHEDULE Infants Between 6-12 Months of Age Local health authorities may recommend measles vaccination of infants between 6-12 months of age in outbreak situations. This population may fail to respond to the components of the vaccine. Safety and effectiveness of mumps and rubella vaccine in infants less than 12	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		months of age have not been established. The younger the infant, the lower the likelihood of seroconversion. Such infants should receive a second dose of M-M-R II at 15 months of age followed by revaccination at 4-6 years of age or 11-12 years of age. OTHER VACCINATION CONSIDERATIONS Non-Pregnant Adolescent and Adult Females Immunization of susceptible non-pregnant adolescent and adult females of childbearing age with live attenuated rubella virus vaccine is indicated if certain precautions are observed. Vaccinating susceptible postpubertal females confers individual protection against subsequently acquiring rubella infection during pregnancy, which in turn prevents infection of the fetus and consequent congenital rubella injury. Women of childbearing age should be advised not to become pregnant for one month after vaccination and should be informed of the reasons for this precaution. If it is practical and if reliable laboratory services are available, women of childbearing age who are potential candidates for vaccination can have serologic tests to determine susceptibility to rubella. However, with the exception of premarital and prenatal screening, routinely performing serologic tests for all women of childbearing age to determine susceptibility (so that vaccine is given only to proven susceptible women) can be effective but is expensive. Also, 2 visits to the health-care provider would be necessary - one for screening and one for vaccination. Accordingly, rubella vaccination of a woman who is not known to be pregnant and has no history of vaccination is justifiable without serologic testing and may be preferable, particularly when costs of serology are high and follow-up of identified susceptible women for vaccination is not assured. Postpubertal females should be informed of the frequent occurrence of generally self-limited arthralgia and/or arthritis beginning 2 to 4 weeks after vaccination. Postpartum Women It has been found convenient in many instances to vaccinate rubella-susceptible women in	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		the immediate postpartum period. <u>OTHER POPULATIONS</u> Previously unvaccinated children older than 12 months who are in contact with susceptible pregnant women should receive live attenuated rubella vaccine (such as that contained in monovalent rubella vaccine or in M-M-R II) to reduce the risk of exposure of the pregnant woman. Individuals planning travel abroad, if not immune, can acquire measles, mumps or rubella and import these diseases to their country. Therefore, prior to international travel, individuals known to be susceptible to one or more of these diseases can receive either a monovalent vaccine (measles, mumps or rubella), or a combination vaccine as appropriate. However, M-M-R II is preferred for persons likely to be susceptible to mumps and rubella; and if monovalent measles vaccine is not readily available, travelers should receive M-M-R II regardless of their immune status to mumps or rubella. Vaccination has been recommended for susceptible individuals in high-risk groups such as college students, health-care workers, and military personnel. <u>POST-EXPOSURE VACCINATION</u> Vaccination of individuals exposed to natural measles may provide some protection if the vaccine can be administered within 72 hours of exposure. If, however, vaccine is given a few days before exposure, substantial protection may be afforded. There is no conclusive evidence that vaccination of individuals recently exposed to natural mumps or natural rubella will provide protection. <u>USE WITH OTHER VACCINES</u> M-M-R II should be given one month before or after administration of other live viral vaccines. M-M-R II has been administered concurrently with live attenuated varicella and inactivated	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Haemophilus influenzae type b (Hib) conjugate vaccines using separate injection sites and syringes. No impairment of immune response to individually tested vaccine antigens was demonstrated. The type, frequency, and severity of adverse experiences observed with M-M-R II were similar to those seen when each vaccine was given alone. Routine administration of DTP (diphtheria, tetanus, pertussis) and/or OPV (oral poliovirus vaccine) concurrently with measles, mumps and rubella vaccines is not recommended because there are limited data relating to the simultaneous administration of these antigens. However, other schedules have been used. Data from published studies concerning the simultaneous administration of the entire recommended vaccine series (i.e., DTP, OPV, MMR, and Hib vaccines, with or without Hepatitis B vaccine), indicate no interference between routinely recommended childhood vaccines (either live, attenuated, or killed). <u>SINGLE DOSE VIAL</u> If the prevention of sporadic measles outbreaks is the sole objective, revaccination with a measles **containing** vaccine should be considered (see appropriate product circular). If concern also exists about immune status regarding mumps or rubella, revaccination with appropriate monovalent or polyvalent vaccine should be considered after consulting the appropriate product circulars. First withdraw the entire volume of diluent into the syringe to be used for reconstitution. Inject all the diluent in the syringe into the vial of lyophilized vaccine, and agitate to mix thoroughly. If the lyophilized vaccine cannot be dissolved, discard. Withdraw the entire contents into a syringe and inject the total volume of reconstituted vaccine **intramuscularly or** subcutaneously. It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of Hepatitis B and other infectious agents from one person to another.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
6.	PROQUAD® (Measles, Mumps, Rubella AND Varicella (Oka/Merck) Virus Vaccine Live, MSD) LYOPHILIZED VACCINE [Live Attenuated Measles, Rubella, Mumps and Varicella Oka Strain Virus]	**INDICATION (POSOLOGY):** Dosage Individuals 12 months through 12 years of age should receive a single dose of ProQuad administered **intramuscularly or** subcutaneously. If a second dose of measles-containing vaccine is to be administered according to applicable official recommendations, then ProQuad may be used for this dose. If the first dose of a measles-containing vaccine is given between 6 months of age and less than 12 months of age (in an at-risk situation such as measles outbreak, or due to official recommendations) the response to the vaccine may be adversely influenced by circulating maternal antibodies. Therefore, another dose of a measles-containing vaccine should be given at 12 months of age or later. A subsequent (third) dose can be administered if warranted by official recommendations for a measles-containing vaccine. At least 1 month should elapse between a dose of M-M-R II and ProQuad. If a second dose of varicella-containing vaccine is administered, there should be a minimum interval of 3 months between doses. Do not give immune globulin (IG) or Varicella-Zoster Immune Globulin (VZIG) concomitantly with ProQuad (see DRUG INTERACTIONS). Method of Administration FOR **INTRAMUSCULAR OR** SUBCUTANEOUS ADMINISTRATION **ONLY**. DO NOT INJECT INTRAVASCULARLY. The vaccine is to be injected in the deltoid region of the upper arm or in the higher anterolateral area of the thigh. CAUTION: A sterile syringe free of preservatives, antiseptics, detergents, and other anti-viral substances must be used for each injection and/or reconstitution of ProQuad because these substances may inactivate the vaccine viruses.	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		To reconstitute the vaccine, use only the diluent supplied because it is free of preservatives or other anti-viral substances, which might inactivate the vaccine viruses. It is important to use a separate sterile syringe and needle for each patient to prevent transmission of infectious agents from one individual to another. Withdraw the entire volume of solvent into a syringe (if a prefilled syringe is available, this step is not necessary). Inject the entire content of the syringe into the vial containing the powder. Gently agitate to dissolve completely. Withdraw the entire content of the reconstituted vaccine from the vial into the same syringe and inject the entire volume. IT IS RECOMMENDED THAT THE VACCINE BE ADMINISTERED IMMEDIATELY AFTER RECONSTITUTION, TO MINIMIZE LOSS OF POTENCY. DISCARD IF RECONSTITUTED VACCINE IS NOT USED WITHIN 30 MINUTES. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Before reconstitution, the lyophilized vaccine is a white to pale yellow compact crystalline plug. ProQuad, when reconstituted, is a pale yellow to light pink liquid.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
7.	Varivax Refrigerated Varicella Virus Vaccine, Live (Oka/Merck) [Varicella, live attenuated]	**INDICATION (POSOLOGY) :** FOR INTRAMUSCULAR OR SUBCUTANEOUS ADMINISTRATION ONLY. Do not inject intravenously. Children 12 months to 12 years of age should receive an approximately 0.5 mL dose administered intramuscularly or subcutaneously. If a second dose is administered, there should be a minimum interval of 3 months between doses (see CLINICAL PHARMACOLOGY). Adolescents and adults 13 years of age and older should receive an approximately 0.5 mL dose administered intramuscularly or subcutaneously at elected date and a second approximately 0.5 mL dose 4 to 8 weeks later. The outer aspect of the upper arm (deltoid region) is the preferred site of injection. <u>Methods of administration</u> <u>Prefilled syringe of diluent:</u> To reconstitute the vaccine, inject all of the diluent (0.7 mL) in the prefilled syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly. Withdraw the entire contents into the syringe and inject the total volume (approximately 0.5 mL) of reconstituted vaccine intramuscularly or subcutaneously, preferably into the outer aspect of the upper arm (deltoid region) or the anterolateral thigh. IT IS RECOMMENDED THAT THE VACCINE BE ADMINISTERED IMMEDIATELY AFTER RECONSTITUTION, TO MINIMIZE LOSS OF POTENCY. DISCARD IF RECONSTITUTED VACCINE IS NOT USED WITHIN 30 MINUTES. Do not freeze reconstituted vaccine. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. VARIVAX Refrigerated when reconstituted is a clear, colorless to pale yellow liquid.	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

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		Vial of diluent: The diluent should be stored separately at room temperature (20 to 25°C, 68 to 77°F), or in the refrigerator. To reconstitute the vaccine, first withdraw 0.7 mL of diluent into the syringe to be used for reconstitution. Inject all of the diluent in the syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly. Withdraw the entire contents into a syringe and inject the total volume (approximately 0.5 mL) of reconstituted vaccine intramuscularly or subcutaneously, preferably into the outer aspect of the upper arm (deltoid region) or the anterolateral thigh. IT IS RECOMMENDED THAT THE VACCINE BE ADMINISTERED IMMEDIATELY AFTER RECONSTITUTION, TO MINIMIZE LOSS OF POTENCY. DISCARD IF RECONSTITUTED VACCINE IS NOT USED WITHIN 30 MINUTES. Do not freeze reconstituted vaccine. CAUTION: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of VARIVAX Refrigerated because these substances may inactivate the vaccine virus. It is important to use a separate sterile syringe and needle for each patient to prevent transmission of infectious agents from one individual to another. To reconstitute the vaccine, use only the diluent supplied, since it is free of preservatives or other anti-viral substances which might inactivate the vaccine virus. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. VARIVAX Refrigerated when reconstituted is a clear, colorless to pale yellow liquid.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
8.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION :** Endometrial Cancer KEYTRUDA, in combination with carboplatin and paclitaxel, followed by KEYTRUDA as monotherapy, is indicated for the treatment of patients with primary advanced or recurrent endometrial carcinoma.	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.
9.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION :** Urothelial Carcinoma KEYTRUDA, in combination with enfortumab vedotin, is indicated for the first-line treatment of unresectable or metastatic urothelial carcinoma in adults. **POSOLOGY :** **General** **Patient Selection** If specified in the indication, select patients for treatment with KEYTRUDA based on the presence of positive PD-L1 expression, MSI-H or dMMR tumor status [see V. Indications]. PD-L1 expression should be evaluated using the PD-L1 IHC 22C3 pharmDx™ kit or equivalent. MSI or MMR tumor status should be evaluated using a validated test. **Recommended Dosing** KEYTRUDA is administered as an intravenous infusion over 30 minutes.	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		The recommended dose of KEYTRUDA in adults is either: • **200mg every 3 weeks or** • **400mg every 6 weeks.** For use in combination, see the prescribing information for the concomitant therapies. When administering KEYTRUDA as part of a combination with intravenous chemotherapy, KEYTRUDA should be administered first. **For urothelial carcinoma patients treated with KEYTRUDA in combination with enfortumab vedotin, administer KEYTRUDA after enfortumab vedotin when given on the same day.** **For urothelial carcinoma patients treated with KEYTRUDA in combination with enfortumab vedotin, the recommended initial dose of enfortumab vedotin is 1.25 mg/kg (up to a maximum of 125 mg for patients≥100 kg) as an intravenous solution on Days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity.** For RCC patients treated with KEYTRUDA in combination with axitinib, see the prescribing information regarding dosing of axitinib. When used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of six weeks or longer [see Clinical Studies (IIId)]. For endometrial carcinoma and RCC patients treated with KEYTRUDA in combination with lenvatinib, the recommended initial dose of lenvatinib is 20 mg orally once daily until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months in patients without disease progression. Patients should be treated with KEYTRUDA until disease progression or unacceptable toxicity. Atypical responses (i.e., an initial transient increase in tumor size or small new lesions within the first few months followed by tumor shrinkage) have been observed. Clinically stable patients with initial evidence of disease progression should remain on treatment until disease progression is confirmed. For adjuvant treatment of melanoma, NSCLC, or RCC, KEYTRUDA should be administered	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		for up to one year or until disease recurrence or unacceptable toxicity. For the neoadjuvant and adjuvant treatment of resectable NSCLC, patients should be treated with neoadjuvant KEYTRUDA in combination with chemotherapy for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as monotherapy for 39 weeks or until disease recurrence or unacceptable toxicity. For the neoadjuvant and adjuvant treatment of high-risk early-stage TNBC, patients should be treated with neoadjuvant KEYTRUDA in combination with chemotherapy for 8 doses of 200 mg every 3 weeks or 4 doses of 400 mg every 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as monotherapy for 9 doses of 200 mg every 3 weeks or 5 doses of 400 mg every 6 weeks or until disease recurrence or unacceptable toxicity. Patients who experience disease progression that precludes definitive surgery or unacceptable toxicity related to KEYTRUDA as neoadjuvant treatment in combination with chemotherapy should not receive KEYTRUDA monotherapy as adjuvant treatment.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
10.	BLINCYTO (Blinatumomab) for injection 35 mcg/vial [Blinatumomab 35 mcg/vial]	**INDICATION :** <u>MRD-positive B-cell Precursor ALL</u> BLINCYTO is indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults. <u>Relapsed or Refractory B-cell Precursor ALL</u> Blincyto is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL) in adults and pediatric patients. <u>B-cell precursor ALL in the Consolidation Phase</u> Blincyto can be used for pediatric and adult patients with Philadelphia chromosome-negative and CD19-positive B-cell precursor ALL (acute lymphoblastic leukemia) in the consolidation phase. **POSOLOGY :** Treatment of B-cell Precursor ALL in the Consolidation Phase • Hospitalization is recommended for the first 3 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and reinitiation (e.g., if treatment is interrupted for 4 or more hours), supervision by a healthcare professional or hospitalization is recommended. • Blincyto is administered as a continuous intravenous infusion delivered at a constant flow rate using an infusion pump. A single cycle of treatment is 28 days (4 weeks) of continuous infusion followed by a 14-day (2-week) treatment-free interval. Patients may receive up to 4 cycles of Blincyto consolidation treatment. • See Table 3 for the recommended daily dose by patient weight. Patients weighing greater than or equal to 45 kg receive a fixed-dose, and for patients weighing less than 45 kg, the dose is calculated using the patient's body surface area (BSA). Table 3. Recommended Dosage for B-cell Precursor ALL in the Consolidation Phase	**AMGEN BIOPHARMACEUTICALS MALAYSIA SDN BHD** Common Ground, 1 Powerhouse, Horizon Penthouse, No. 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Cycle(s)
1-4</td><td>Patients Weighing 45 kg or More (Fixed-dose)</td><td>Patients Weighing Less than 45 kg (BSA-based dose)</td></tr>
<tr><td>Days 1-28</td><td colspan="2">28 mcg/day</td><td>15 mcg/m^2/day
(not to exceed 28 mcg/day)</td></tr>
<tr><td>Days 29-42</td><td>14-day treatment-free interval</td><td>14-day treatment-free interval</td></tr>
</table>

Intrathecal chemotherapy prophylaxis is recommended before and during Blincyto therapy to prevent central nervous system ALL relapse.
Premedicate with dexamethasone

For adult patients, premedicate with prednisone 100 mg intravenously or equivalent (e.g., dexamethasone 16 mg) 1 hour prior to the first dose of BLINCYTO in each cycle.
For pediatric patients, premedicate with 5 mg/m^2 of dexamethasone, to a maximum dose of 20 mg prior to the first dose of Blincyto in the first cycle and when restarting an infusion after an interruption of 4 or more hours in the first cycle.

For administration of BLINCYTO:

o See Section 2.5 for infusion over 24 hours, 48 hours, 72 hours, or 96 hours.
</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>11.</td><td>XEOMIN powder for solution for injection 50 LD50 units

XEOMIN powder for solution for injection 100 LD50 units

[Clostridium Botulinum neurotoxin type A]</td><td>
INDICATION :

Xeomin is indicated in adults for use for the treatment of:

• Chronic sialorrhea due to neurological disorders

Xeomin is indicated for the symptomatic treatment in children and adolescents aged 2 to 17 years and weighing ≥12 kg of:

• Chronic sialorrhea due to neurological / neurodevelopmental disorders

POSOLOGY:

Chronic sialorrhea (adults)

A reconstituted solution at a concentration of 5 units/0.1 ml should be used.

XEOMIN is injected into the parotid and submandibular glands on both sides (per treatment four injections in total). The dose is divided with a ratio of 3:2 between the parotid and submandibular glands.

Table 4: Treatment doses per gland – Chronic sialorrhea (adults)
<table>
<tr><th rowspan="2">Glands</th><th>Dose per side</th><th>Volume per injection</th></tr>
<tr><td>[Units]</td><td>[ml]</td></tr>
<tr><td>Parotid glands</td><td>30</td><td>0.6</td></tr>
<tr><td>Submandibular glands</td><td>20</td><td>0.4</td></tr>
</table>
The injection site should be close to the centre of the gland.
</td><td>TT MEDICAL MANAGEMENT SDN BHD
A-3A-03, Ekocheras, No 693, Batu 5, Jalan Cheras,
56000 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.</td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
The recommended total dose per treatment session is 100 units.

Repeat treatment should be no more frequent than every 16 weeks.

Treatment intervals should be determined based on the actual clinical need of the individual patient.

Chronic sialorrhea (children/adolescents)

A reconstituted solution at a concentration of 2.5 units/0.1 ml should be used.

XEOMIN is injected into the parotid and submandibular glands on both sides (per treatment four injections in total). The body-weight adjusted dose is divided with a ratio of 3:2 between the parotid and submandibular glands as indicated in the table below.

Treatment doses should be administered by body weight class and the total dose should not exceed 75 units per treatment session. No dosing recommendations can be made for children weighting less than 12 kg.

Table 5: Treatment doses by body weight class – Chronic sialorrhea (children/adolescents)
<table>
<tr><td>Body weight</td><td colspan="2">Parotid gland, each side</td><td colspan="2">Submandibular gland, each side</td><td>Total dose, both glands, both sides</td></tr>
<tr><td></td><td>Dose per gland</td><td>Volume per injection</td><td>Dose per gland</td><td>Volume per injection</td><td></td></tr>
<tr><td>[kg]</td><td>[Units]</td><td>[ml]</td><td>[Units]</td><td>[ml]</td><td>[Units]</td></tr>
<tr><td>≥ 12 and < 15</td><td>6</td><td>0.24</td><td>4</td><td>0.16</td><td>20</td></tr>
<tr><td>≥ 15 and < 19</td><td>9</td><td>0.36</td><td>6</td><td>0.24</td><td>30</td></tr>
<tr><td>≥ 19 and < 23</td><td>12</td><td>0.48</td><td>8</td><td>0.32</td><td>40</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>≥ 23 and < 27</td><td>15</td><td>0.60</td><td>10</td><td>0.40</td><td>50</td></tr>
<tr><td>≥ 27 and < 30</td><td>18</td><td>0.72</td><td>12</td><td>0.48</td><td>60</td></tr>
<tr><td>≥ 30</td><td>22.5</td><td>0.90</td><td>15</td><td>0.60</td><td>75</td></tr>
</table>
The injection site should be close to the centre of the gland.
Repeat treatment should be no more frequent than every 16 weeks.
Treatment intervals should be determined based on the actual clinical need of the individual patient
Chronic sialorrhea (adults/children/adolescents)
After reconstitution the XEOMIN solution is injected intraglandularly using a suitable sterile needle (e.g. 27-30gauge/0.30-0.40 mm diameter/12.5 mm length).
In adults, anatomic landmarks or ultrasound guidance are both possible for the localisation of the involved salivary glands, however the ultrasound guided method should be preferred, because it could result in a better therapeutic outcome.
For the treatment of children and adolescents ultrasound guidance should be used. Local anaesthesia (such as local anaesthetic cream), sedation, or anaesthesia in combination with sedation may be offered to children and adolescents prior to injection after a careful benefit-risk evaluation and per local site practice.
</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>12.</td><td>Reblozyl 25 mg powder for solution for injection

[Luspatercept 25mg/ vial]

Reblozyl 75 mg powder for solution for injection

[Luspatercept 75mg/ vial]</td><td>
INDICATION :

Reblozyl is indicated in adults for the treatment of transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS).

POSOLOGY:

Reblozyl treatment should be initiated by a physician experienced in treatment of haematological diseases.

<u>Posology</u>

Prior to each Reblozyl administration, the haemoglobin (Hb) level of patients should be assessed. In case of a red blood cell (RBC) transfusion occurring prior to dosing, the pre-transfusion Hb level must be considered for dosing purposes.

The recommended starting dose of Reblozyl is 1.0 mg/kg administered once every 3 weeks.

• Myelodysplastic syndromes

The recommended desired Hb concentration range is between 10 g/dL and 12 g/dL. Dose increase for insufficient response is provided below.

Table 1: Dose increase for insufficient response
<table>
<tr><th>Dose at 1 mg/kg</th><th>Dose increase</th></tr>
<tr><td>If after at least 2 consecutive doses at 1.0 mg/kg, a patient:

• is not RBC transfusion- free, or
• does not reach Hb concentration of ≥ 10 g/dL and the Hb increase is < 1 g/dL</td><td>• Dose should be increased to 1.33 mg/kg</td></tr>
</table>
</td><td>DKSH MALAYSIA SDN. BHD.
B-11-01, The Ascent, Paradigm,
No. 1, Jalan SS7/26A, Kelana Jaya,
47301 Petaling Jaya, Selangor.</td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>Dose at 1.33 mg/kg</th><th>Dose increase</th></tr>
<tr><td>If after at least 2 consecutive doses at 1.33 mg/kg, a patient:
is not RBC transfusion- free, or
does not reach Hb concentration of ≥ 10 g/dL and the Hb increase is < 1 g/dL</td><td>Dose should be increased to 1.75 mg/kg</td></tr>
</table>
The dose increase should not occur more frequently than every 6 weeks (2 administrations) and should not exceed the maximum dose of 1.75 mg/kg every 3 weeks. The dose should not be increased immediately after a dose delay.
For patients with a pre-dose Hb level of > 9 g/dL and who have not yet achieved transfusion independence, a dose increase may be required at the physician’s discretion; the risk of Hb increasing above the target threshold with concomitant transfusion cannot be excluded.
If a patient loses response (i.e., transfusion independence), the dose should be increased by one dose level (see Table 2).
Transfusion-dependent β-thalassaemia
In patients who do not achieve a response, defined as a reduction in RBC transfusion burden of at least a third after ≥ 2 consecutive doses (6 weeks), at the 1.0 mg/kg starting dose, the dose should be increased to 1.25 mg/kg. The dose should not be increased beyond the maximum dose of 1.25 mg/kg every 3 weeks.
If a patient loses response (if the RBC transfusion burden increases again after an initial response) the dose should be increased by one dose level (see Table 3).
<u>Increase to next dose level</u>
Increase to next dose level based on current dose is provided below.
</td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>

Table 2: Increase to next dose level for MDS

<table>
<tr><th>Current dose</th><th>Increased dose</th></tr>
<tr><td>0.8 mg/kg</td><td>1 mg/kg</td></tr>
<tr><td>1 mg/kg</td><td>1.33 mg/kg</td></tr>
<tr><td>1.33 mg/kg</td><td>1.75 mg/kg</td></tr>
</table>

Table 3: Increase to next dose level for b-thalassaemia

<table>
<tr><th>Current dose</th><th>Increased dose</th></tr>
<tr><td>0.8 mg/kg</td><td>1 mg/kg</td></tr>
<tr><td>1 mg/kg</td><td>1.25 mg/kg</td></tr>
</table>

<u>Dose reduction and dose delay</u>

In case of Hb increase > 2 g/dL within 3 weeks in absence of transfusion compared with the Hb value at previous dose, Reblozyl dose should be reduced by one dose level.

If the Hb is ≥ 12 g/dL in the absence of transfusion for at least 3 weeks, the dose should be delayed until the Hb is ≤ 11.0 g/dL. If there is also a concomitant rapid increase in Hb from the Hb value at previous dose (> 2 g/dL within 3 weeks in absence of transfusion), a dose reduction to one step down should be considered after the dose delay.

Dose should not be reduced below 0.8 mg/kg.

Dose reductions during treatment with luspatercept are provided below.

</td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>

Table 4: Dose reductions for MDS

<table>
<tr><th>Current dose</th><th>Dose reduction</th></tr>
<tr><td>1.75 mg/kg</td><td>1.33 mg/kg</td></tr>
<tr><td>1.33 mg/kg</td><td>1 mg/kg</td></tr>
<tr><td>1 mg/kg</td><td>0.8 mg/kg</td></tr>
</table>

Table 5: Dose reductions for β-thalassaemia

<table>
<tr><th>Current dose</th><th>Dose reduction</th></tr>
<tr><td>1.25 mg/kg</td><td>1 mg/kg</td></tr>
<tr><td>1 mg/kg</td><td>0.8 mg/kg</td></tr>
</table>

<u>Dose modification due to adverse reactions</u>

Instructions on dose interruptions or reductions for luspatercept treatment-related adverse reactions are outlined in Table 6.

Table 6: Dose modification instructions

<table>
<tr><th>Treatment-related adverse reactions*</th><th>Dose instructions</th></tr>
<tr><td>Grade 2 adverse reactions, including Grade 2 hypertension</td><td>• Interrupt treatment
• Restart at previous dose when adverse reaction has improved or returned to baseline</td></tr>
<tr><td>Grade ≥ 3 hypertension</td><td>• Interrupt treatment
• Restart at reduced dose once the blood pressure is controlled</td></tr>
</table>

</td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td></td><td>as per dose reduction guidance</td></tr>
<tr><td>Other persistent Grade ≥ 3 adverse reactions</td><td>• Interrupt treatment
• Restart at previous dose or at reduced dose when adverse reaction has improved or returned to baseline as per dose reduction guidance</td></tr>
<tr><td>Extramedullary haemopoiesis (EMH) masses causing serious complications</td><td>• Discontinue treatment</td></tr>
</table>
* Grade 1: mild; Grade 2: moderate; Grade 3: severe; and Grade 4: life-threatening.

<u>Missed doses</u>

In case of a missed or delayed scheduled treatment administration, the patient should be administered Reblozyl as soon as possible and dosing continued as prescribed with at least 3 weeks between doses.

<u>Patients experiencing a loss of response</u>

If patients experience a loss of response to Reblozyl, causative factors (e.g. a bleeding event) should be assessed. If typical causes for a loss of haematological response are excluded, dose increase should be considered as described above for the respective indication being treated (see Table 2 and Table 3).

<u>Discontinuation</u>

Reblozyl should be discontinued if patients do not experience a reduction in transfusion burden (for transfusion-dependent β-thalassaemia patients) or a decrease in transfusion burden including no increase from baseline Hb (for MDS patients) after 9 weeks of treatment (3 doses) at the maximum dose level if no alternative explanations for response failure are found (e.g. bleeding, surgery, other concomitant illnesses) or if unacceptable toxicity occurs at any time.
</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<u>Special populations</u> Elderly No starting dose adjustment is required for Reblozyl (see section 5.2). Limited data are available in β-thalassaemia patients ≥ 60 years of age. Hepatic impairment No starting dose adjustment is required for patients with total bilirubin (BIL) > upper limit of normal (ULN) and/or alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 3 x ULN (see section 5.2). No specific dose recommendation can be made for patients with ALT or AST ≥ 3 x ULN or liver injury CTCAE Grade ≥ 3 due to lack of data (see section 5.2). Renal impairment No starting dose adjustment is required for patients with mild or moderate renal impairment (individual estimated glomerular filtration rate [eGFR] 30 to 89 mL/min). No specific dose recommendation can be made for patients with severe renal impairment (individual eGFR < 30 mL/min) due to lack of clinical data. **Patients with renal impairment at baseline have been observed to have higher exposure. Consequently, these patients should be closely monitored for adverse reactions and dose adjustment should be managed accordingly (see Table 6).** Paediatric population The safety and efficacy of Reblozyl in paediatric or adolescent patients (under 18 years of age) has not been established. For non-clinical data, see section Preclinical safety data. <u>Method of administration</u> For subcutaneous use. After reconstitution, Reblozyl solution should be injected subcutaneously into the upper arm, thigh or abdomen. The exact total dosing volume of the reconstituted solution required for the patient should be calculated and slowly withdrawn from the single-dose vial(s) into a syringe.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		The recommended maximum volume of medicinal product per injection site is 1.2 mL. If more than 1.2 mL is required, the total volume should be divided into separate similar volume injections and administered across separate sites **using the same anatomical location but on opposite sides of the body.** If multiple injections are required, a new syringe and needle must be used for each subcutaneous injection. No more than one dose from a vial should be administered. If the Reblozyl solution has been refrigerated after reconstitution, it should be removed from the refrigerator 15-30 minutes prior to injection to allow it to reach room temperature. This will allow for a more comfortable injection. For instructions on reconstitution of the medicinal product before administration, see section 6.6. section Special precautions for disposal and other handling.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>13.</td><td>Padcev 20mg Powder for Concentrate for Solution for Infusion

[Enfortumab vedotin 20mg]

Padcev 30mg Powder for Concentrate for Solution for Infusion

[Enfortumab vedotin 30mg]</td><td>INDICATION :

PADCEV, in combination with pembrolizumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial cancer (mUC).

POSOLOGY:

Posology

As monotherapy, the recommended dose of enfortumab vedotin is 1.25 mg/kg (up to a maximum of 125 mg for patients ≥100 kg) administered as an intravenous infusion over 30 minutes on Days 1, 8 and 15 of a 28-day cycle until disease progression or unacceptable toxicity.

When given in combination with pembrolizumab, the recommended dose of enfortumab vedotin is 1.25 mg/kg (up to a maximum of 125 mg for patients ≥100 kg) administered as an intravenous infusion over 30 minutes on Days 1 and 8 of every 3-week (21-day) cycle until disease progression or unacceptable toxicity. The recommended dose of pembrolizumab is either 200 mg every 3 weeks or 400 mg every 6 weeks administered as an intravenous infusion over 30 minutes. Patients should be administered pembrolizumab after enfortumab vedotin when given on the same day. Refer to the pembrolizumab package insert for additional dosing information of pembrolizumab.

Table 1. Recommended dose reductions for enfortumab vedotin adverse reactions
<table><tr><th></th><th>Dose level</th></tr><tr><td>Starting dose</td><td>1.25 mg/kg up to 125 mg</td></tr><tr><td>First dose reduction</td><td>1.0 mg/kg up to 100 mg</td></tr></table></td><td>ASTELLAS PHARMA MALAYSIA SDN BHD
Unit 9.02 And 9.03, Level 9, Corporate Tower 2, Pavilion Damansara Heights 3, Jalan Damanlela,
Pusat Bandar Damansara, 50490 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.</td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Second dose reduction</td><td>0.75 mg/kg up to 75 mg</td></tr>
<tr><td>Third dose reduction</td><td>0.5 mg/kg up to 50 mg</td></tr>
</table>

Dose modifications

Table 2. Dose interruption, reduction and discontinuation in patients with locally advanced or metastatic urothelial cancer
<table>
<tr><th>Adverse reaction</th><th>Severity*</th><th>Dose modification*</th></tr>
<tr><td rowspan="3">Skin reactions</td><td>Grade 2 worsening
Grade 2 with fever
Grade 3</td><td>● Withhold until Grade ≤1
● Referral to specialised care should be considered
● Resume at the same dose level or consider dose reduction by one dose level (see Table 1)</td></tr>
<tr><td>Suspected Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) or
bullous lesions</td><td>● Immediately withhold and refer to specialised care.</td></tr>
<tr><td>Confirmed SJS or TEN; Grade 4 or recurrent Grade 3</td><td>● Permanently discontinue.</td></tr>
<tr><td>Hyperglycemia</td><td>Blood glucose >13.9 mmol/L (>250 mg/dL)</td><td>● Withhold until elevated blood glucose has improved to ≤13.9 mmol/L (≤250 mg/dL)
● Resume treatment at the same dose level</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Pneumonitis/
interstitial lung disease (ILD)</td><td>Grade 2</td><td>● Withhold until Grade ≤1, then resume at the same dose or consider dose reduction by one dose level (see Table 1)</td></tr>
<tr><td></td><td>Grade ≥3</td><td>● Permanently discontinue.</td></tr>
<tr><td>Peripheral neuropathy</td><td>Grade 2</td><td>● Withhold until Grade ≤1
● For first occurrence, resume treatment at the same dose level
● For a recurrence, withhold until Grade ≤1 then, resume treatment reduced by one dose level (see Table 1)</td></tr>
<tr><td></td><td>Grade ≥3</td><td>Permanently discontinue.</td></tr>
</table>
*Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events Version 5.0 (NCI-CTCAE v5.0) where Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe and Grade 4 is life threatening

Special populations

Elderly

No dose adjustment is required in patients ≥65 years of age (see section 5.2).

Patients with renal impairment

No dose adjustment is required in patients with mild [creatinine clearance (CrCL) >60–90 mL/min], moderate (CrCL 30–60 mL/min) or severe (CrCL 15–<30 mL/min) renal impairment. Enfortumab vedotin has not been evaluated in patients with end stage renal disease (CrCL <15 mL/min) (see section 5.2).
</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 411, 7 Ogos 2025

Products approved for additional indication (DCA 411 – 7 August 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Patients with hepatic impairment No dose adjustment is required in patients with mild hepatic impairment [total bilirubin of 1 to 1.5 × upper limit of normal (ULN) and AST any, or total bilirubin ≤ ULN and AST > ULN]. Enfortumab vedotin has only been evaluated in a limited number of patients with moderate and severe hepatic impairment. Hepatic impairment is expected to increase the systemic exposure to MMAE (the cytotoxic drug); therefore, patients should be closely monitored for potential adverse events. Due to the sparsity of the data in patients with moderate and severe hepatic impairment, no specific dose recommendation can be given (see section 5.2). Pediatric population The safety and efficacy of enfortumab vedotin in pediatric patients have not been established. <u>Method of administration</u> PADCEV is for intravenous use. The recommended dose must be administered by intravenous infusion over 30 minutes. Enfortumab vedotin must not be administered as an intravenous push or bolus injection. For instructions on reconstitution and dilution of the medicinal product before administration, see section 6.6.	