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| **Name, Restriction,****Manner of administration and form** | **PBS item code** | **Max.****Amount** | **№.of****Rpts** | **Manufacturer** |
| TRASTUZUMAB EMTANSINE Injection  | 10282E (Public)10281D (Private) | 450 mg | 8 | Roche Products Pty Ltd |
| **Available brands** |
| Kadcyla(trastuzumab emtansine 160 mg injection, 1 vial) |
| Kadcyla(trastuzumab emtansine 100 mg injection, 1 vial) |

**Restriction Summary 9613 / Treatment of Concept: 9599**

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| **Concept ID**(for internal Dept. use) | **Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals  |
| **Prescriber type:** [ ] Dental [x] Medical Practitioners [ ] Nurse practitioners [ ] Optometrists [ ] Midwives |
| **Restriction Type – assessment time by Services Australia – Method of obtaining authority approval (if Authority Required):**[x]  Authority Required – non-immediate/delayed assessment by Services Australia (in-writing only via mail/postal service or electronic upload to Hobart; requires at least one concept ID to be marked as ‘FULL’ for full assessment by Services Australia) |
| **Episodicity:** blank |
| **Severity:** Metastatic (Stage IV) |
| **Condition:** HER2 positive breast cancer |
| 14661 | **Indication:** Metastatic (Stage IV) HER2 positive breast cancer |
|  | **Treatment Phase:** Initial treatment |
| 14665 | **Clinical criteria:** |
| 14664 | Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion |
|  | **AND** |
| 15303 | **Clinical criteria:** |
| 15301 | The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; or |
| 15302 | The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab |
|  | **AND** |
| 10859 | **Clinical criteria:** |
| 10858 | Patient must have a WHO performance status of 0 or 1 |
|  | **AND** |
| 7910 | **Clinical criteria:** |
| 7909 | The treatment must be as monotherapy |
|  | **AND** |
| 7745 | **Clinical criteria:** |
| 7744 | The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure |
| 26111FULL | **Prescribing Instructions:**Authority applications for initial treatment must be made in writing and must include:(a) a completed authority prescription form; and(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:(i) details of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease;(ii) dates of treatment with trastuzumab and pertuzumab; and(iii) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or(iv) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment.If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application |
| 24537 | **Prescribing Instructions:**Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval |
| 7753CAR | **Administrative Advice:**Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hposOr mailed to:Services AustraliaComplex DrugsReply Paid 9826HOBART TAS 7001 |
| 7607 | **Administrative Advice:** No increase in the maximum number of repeats may be authorised |
| 25594 | **Administrative Advice:** Increased maximum amounts can be requested where a patient's weight is greater than 125 kg |

CAR: Services Australia complex assessment required; FULL: full assessment required

**Restriction Summary 10256 / Treatment of Concept: 10214**

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| **Concept ID**(for internal Dept. use) | **Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals  |
| **Prescriber type:** [ ] Dental [x] Medical Practitioners [ ] Nurse practitioners [ ] Optometrists [ ] Midwives |
| **Restriction Type – assessment time by Services Australia – Method of obtaining authority approval (if Authority Required):**[x]  Authority Required – immediate/real time assessment by Services Australia (telephone/online application avenues) |
| 14661 | **Indication:** Metastatic (Stage IV) HER2 positive breast cancer |
|  | **Treatment Phase:** Continuing treatment |
| 25626 | **Clinical criteria:** |
| 25625 | Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer |
|  | **AND** |
| 11485 | **Clinical criteria:** |
| 11484 | Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug |
|  | **AND** |
| 7910 | **Clinical criteria:** |
| 7909 | The treatment must be as monotherapy |
|  | **AND** |
| 7745 | **Clinical criteria:** |
| 7744 | The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure |
| 11473 | **Prescribing Instructions:**A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.  |
| 25627 | **Prescribing Instructions:**The treatment must not exceed a lifetime total of one continuous course for this PBS indication. |
| 14726CAR | **Administrative Advice:**Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  |

CAR: Services Australia complex assessment required