Medicines for the treatment of gastrointestinal stromal tumours

Drug utilisation sub-committee (DUSC)

April 2025

## Abstract

### Purpose

To review the utilisation of medicines for the treatment of gastrointestinal stromal tumours (GIST) as requested by DUSC at its October 2024 meeting.

### Date of listing on the Pharmaceutical Benefits Scheme (PBS)

* Imatinib was PBS listed for the treatment of metastatic or unresectable malignant GIST on 1 February 2004. Its listing was extended to include adjuvant GIST on 1 September 2011.
* Sunitinib was PBS listed for the treatment of metastatic GIST on 1 December 2009.
* Ripretinib was PBS listed for the treatment of metastatic GIST on 1 December 2021.

### Data Source / methodology

Data extracted from the PBS database maintained by Department of Health, Disability and Ageing, processed by Services Australia were used for the analyses.

### Key Findings

* The utilisation of the adjuvant and metastatic GIST listings has been stabilising since the second quarter of 2022.
* In 2023, 1,431 patients were supplied 9,940 prescriptions for the treatment of GIST. In 2022, 1,371 patients were supplied 9,406 prescriptions for the treatment of GIST.
* Overall, a greater number of patients were treated with PBS listed medicines for metastatic GIST compared to adjuvant GIST.
* Most metastatic GIST patients were treated with imatinib and have remained on imatinib as first-line therapy.

# Purpose of analysis

To review the utilisation of medicines for the treatment of gastrointestinal stromal tumours as requested by DUSC at its October 2024 meeting.

# Background

## Clinical situation

GIST is a rare cancer of the stomach and bowels.[[1]](#footnote-2) Most GIST are caused by activation of the KIT proto-oncogene, which encodes a tyrosine-kinase receptor. GIST can be readily identified by testing for a specific marker, the expression of KIT (CD117), with immunohistochemical staining.

Surgery is the sole treatment for primary localised GIST. Patients at high risk of recurrence and who have resectable GIST may be offered imatinib adjuvant therapy. Patients remain on imatinib therapy unless they experience a recurrence, at which time the cancer is considered metastatic. Patients who have metastatic or unresectable GIST are treated with imatinib and failing this, treated with sunitinib followed by ripretinib. Ripretinib is available on the PBS for patients with metastatic or unresectable malignant GIST who have progressed on all other PBS-listed drugs for this indication.

## Pharmacology

Imatinib, ripretinib and sunitinib belong to a group of anti-cancer medicines known as tyrosine kinase inhibitors which slow down the growth or spread of tumour cells.[[2]](#footnote-3),[[3]](#footnote-4),[[4]](#footnote-5)

## Therapeutic Goods Administration (TGA) approved indications

**Imatinib2**

Imatinib is TGA indicated for:

* the treatment of patients with KIT (CD117) positive unresectable and/or metastatic malignant GIST.
* adjuvant treatment of adult patients at high risk of recurrence following complete gross resection of KIT (CD117)-positive primary GIST.

Imatinib is also TGA indicated for:

* treatment of patients with chronic myeloid leukaemia (CML).
* treatment of adult patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy.
* treatment of adult patients with relapsed or refractory Ph+ ALL as monotherapy.
* treatment of adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet‐derived growth factor receptor (PDGFR) gene re‐ arrangements, where conventional therapies have failed.
* treatment of adult patients with aggressive systemic mastocytosis (ASM), where conventional therapies have failed.
* treatment of adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL).
* treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).

**Sunitinib3**

Sunitinib is TGA indicated for the treatment of GIST after failure of imatinib mesilate treatment due to resistance or intolerance.

Sunitinib is also TGA indicated for the treatment of advanced renal cell carcinoma (RCC) and the treatment of unresectable, well-differentiated pancreatic neuroendocrine tumours (pancreatic NET).

**Ripretinib4**

Ripretinib is TGA indicated for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

Ripretinib is subject to additional monitoring in Australia. Healthcare professionals are asked to report any suspected adverse events to the TGA.

## Dosage and administration

Table 1: Dosage and administration of PBS listed medicines for GIST

| Product | Dose and frequency of administration  |
| --- | --- |
| Imatinib  | Doses of 400 mg or 600 mg should be administered orally once daily.  |
| Ripretinib  | Three 50 mg tablets orally once daily with or without food until disease progression or unacceptable toxicity. |
| Sunitinib  | 50 mg taken orally once daily for 4 consecutive weeks followed by a 2 week rest period to comprise a complete cycle of 6 weeks.  |

Source: TGA Product Information.

The current Product Information (PI) and Consumer Medicine Information (CMI) are available from [the TGA (Product Information)](http://tga.gov.au/hp/information-medicines-pi.htm) and [the TGA (Consumer Medicines Information)](http://www.tga.gov.au/consumers/information-medicines-cmi.htm).

## PBS listing details (as at December 2024)

Brand name and manufacturer details can be found in Appendix A.

**Adjuvant GIST**

Imatinib is the only PBS listed medicine for the treatment of adjuvant GIST.

Table 2: PBS listing of imatinib for adjuvant GIST

| **Item****code** | **Name, form & strength, pack size** | **Max. qty.**  | **Rpts**  | **DPMQ** |
| --- | --- | --- | --- | --- |
| 5443L11784F | imatinib 100 mg tablet, 60 | 60 | 5 | $149.09 |
| 12759M12710Y | imatinib 100 mg capsule, 60 | 60 | 5 | $149.09 |
| 5444M11788K | imatinib 400 mg tablet, 30 | 30 | 5 | $289.69 |
| 12681K12711B | imatinib 400 mg capsule, 30 | 30 | 5 | $289.69 |

Source: the [PBS website](http://www.pbs.gov.au/pbs/home).

Note: Pharmaceutical benefits that have the form imatinib tablet and imatinib capsule are equivalent for the purposes of substitution.

**Metastatic GIST**

There are currently three PBS listed medicines for the treatment of metastatic GIST:

* imatinib (first-line)
* sunitinib (second-line)
* ripretinib (later-line).

Table 3: PBS listing of imatinib for metastatic GIST

| **Item****code** | **Name, form & strength, pack size** | **Max. qty.**  | **Rpts**  | **DPMQ** |
| --- | --- | --- | --- | --- |
| 9111M11787J | imatinib 100 mg tablet, 60 | 60 | 2 | $149.09 |
| 12709X12722N | Imatinib 100 mg capsule, 60 | 60 | 2 | $149.09 |
| 9112N11778X | imatinib 400 mg tablet, 30 | 30 | 2 | $289.69 |
| 12754G12723P | imatinib 400 mg capsule, 30 | 30 | 2 | $289.69 |
| 12926H12919Y | imatinib 600 mg tablet, 30 | 30 | 2 | $560.09 |

Source: the [PBS website](http://www.pbs.gov.au/pbs/home).

Notes:

* Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system.
* No increase in the maximum number of repeats may be authorised.
* Pharmaceutical benefits that have the form imatinib tablet and imatinib capsule are equivalent for the purposes of substitution.

Table 4: PBS listing of sunitinib for metastatic GIST

| **Item****code** | **Name, form & strength, pack size** | **Max. qty.**  | **Rpts**  | **DPMQ** |
| --- | --- | --- | --- | --- |
| 9488J11266Y | sunitinib 12.5 mg capsule, 28 | 28 | 1 | $665.21 |
| 9489K11253G | sunitinib 25 mg capsule, 28 | 28 | 1 | $1,294.65 |
| 10503T11256K | sunitinib 37.5 mg capsule, 28 | 28 | 1 | $1,907.75 |
| 9490L11250D | sunitinib 50 mg capsule, 28  | 28 | 1 | $2,533.10 |

Source: the [PBS website](http://www.pbs.gov.au/pbs/home).

Notes:

* Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system. Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) or mailed to Services Australia.
* No increase in the maximum quantity or number of units may be authorised.
* No increase in the maximum number of repeats may be authorised.

Table 5: PBS listing of ripretinib for metastatic GIST

| **Item** **code** | **Name, form & strength, pack size** | **Max. qty.** | **Rpts** | **DPMQ** |
| --- | --- | --- | --- | --- |
| 12764T | ripretinib 50 mg tablet, 90 | 90 | 1 | $16,304.54 |

Source: the [PBS website](http://www.pbs.gov.au/pbs/home).

Notes:

* No increase in the maximum quantity or number of units may be authorised.
* No increase in the maximum number of repeats may be authorised.
* Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system or by telephone by contacting Services Australia.
* Special Pricing Arrangements apply.

### Restriction (abridged)

**Adjuvant GIST**

Table 6: PBS restriction of imatinib for the treatment of adjuvant GIST

|  |  |  |
| --- | --- | --- |
| **Medicine** | **Initial treatment** | **Continuing treatment** |
| Imatinib | Authority Required (online/telephone)* adjuvant to complete surgical resection
* at high risk of recurrence following resection
* histological confirmation of CD117
 | Authority Required (STREAMLINED)* treatment adjuvant to resection (as initial prescription)
* at high risk of recurrence (as initial script)
* initial PBS authority treatment approved
* must not exceed 400 mg/day and total time 36 months

High risk criteria = GIST 5cm with mitotic count >5/50 high power fields or GIST >10cm or GIST >10/50 high power fields  |

**Metastatic GIST**

Table 7: PBS restrictions of medicines for the treatment of metastatic GIST

| **Medicine** | **Initial treatment**  | **Continuing treatment** |
| --- | --- | --- |
| Imatinib | Authority Required (online/telephone)* must not be resectable
* histological confirmation of CD117
* must be commenced at a

dose not exceeding 400 mg per day * treatment must not exceed 3 months
 | Authority Required (STREAMLINED)* must not be resectable
* must have previously received PBS-subsidised treatment
* dose must not exceed 600 mg per day
 |
| Sunitinib | Authority Required (online/mail)* must not be resectable
* must be monotherapy
* WHO performance 2 or less
* must have failed/intolerant to imatinib
 | Authority Required (STREAMLINED)* must not be resectable
* must have had initial authority script for GIST
* must be monotherapy
* WHO performance status of 2 or less
* must not be progressive disease
 |
| Ripretinib  | Authority Required (online/telephone)* must not be resectable
* must be monotherapy
* WHO performance status of 2 or less
* Condition must have progressed despite treatment with all drugs PBS listed for this indication
 | Authority Required (online/telephone)* must not be resectable
* must have received PBS-subsidised treatment with this drug for this condition
* monotherapy
* not developed disease progression while receiving treatment
 |

For details of the current PBS listing refer to the [PBS website](file:///%5C%5Ccentral.health%5CDFSGroupData%5CSites%5CCO1%5CCO%5CPBD%5CPEB%5CEVAL%5CDUSC%5CDUSC%20Documents%5CPredicted%20vs%20actual%20usage%5Cpbs.gov.au).

### Changes to listing

Table 8 shows the changes to PBS listings of medicines for the treatment of GIST.

Table 8: Changes of PBS listing of GIST medicines

|  |  |
| --- | --- |
| **Date** | **Change to listing** |
| 1 August 2004 | The maximum dose per day for imatinib for metastatic GIST was changed from 400 mg to 600 mg on 1 August 2004. |
| 1 December 2009 | Sunitinib was PBS listed for the treatment of metastatic or unresectable malignant GIST after failure of imatinib mesylate treatment due to resistance or intolerance. |
| 1 September 2011 | The PBS listing of imatinib was extended for adjuvant treatment of a patient at high risk of recurrence following complete resection of primary GIST. Treatment duration was limited to 12 months. |
| 1 December 2013 | The PBS listing of imatinib for adjuvant treatment of a patient at high risk of recurrence following complete resection of primary GIST was extended to allow a total of 36 months of treatment (initial plus continuing therapy). |
| 1 September 2019 | Initial access to imatinib was changed from Authority Required (Written) to Authority Required (Telephone). |
| 1 November 2021 | The capsule form of imatinib was PBS listed. |
| 1 December 2021 | Ripretinib was PBS listed for the treatment of metastatic GIST after failure of or intolerance to imatinib and sunitinib. |
| 1 April 2022 | Imatinib 600 mg tablets for the treatment of metastatic GIST was PBS listed. |
| 1 September 2022 | The initial listing of sunitinib was updated as part of the Department of Health, Disability and Ageing’s digital transformation of Authority Required (Written) PBS listings. Real time assessment of authority requests became available through Services Australia’s Online PBS Authorities (OPA) system, via Health Professional Online Services (HPOS).[[5]](#footnote-6) |

Current PBS listing details are available from the [PBS website](file:///%5C%5Ccentral.health%5CDFSGroupData%5CSites%5CCO1%5CCO%5CPBD%5CPEB%5CEVAL%5CDUSC%5CDUSC%20Documents%5CPredicted%20vs%20actual%20usage%5Cpbs.gov.au).

## Relevant aspects of consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)

**July 2009 - sunitinib**

The PBAC recommended an extension to the listing of sunitinib on the PBS to include the treatment of a metastatic or unresectable malignant gastrointestinal stromal tumour on the basis of high clinical need and a high but acceptable cost-effectiveness ratio compared with best supportive care.

For further details refer to the [Public Summary Document](https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2009-07/pbac-psd-sunitinib-jul09) from the July 2009 PBAC meeting.

**March 2011 - imatinib**

The PBAC agreed that there was a high clinical need for the use of imatinib in the adjuvant treatment of GIST, a rare disease, in a small population where patient numbers were low (less than 10,000 per year in year 5), and that the financial cost to the PBS was also relatively low. The PBAC noted that the revised ICER calculated using the same model and the price decrease was estimated to be in the range of $15,000 - $45,000/QALY compared with $45,000 - $75,000/QALY in the November 2010 submission.

For further details refer to the [Public Summary Document](https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2011-03/pbac-psd-imatinib-march11) from the March 2011 PBAC meeting.

**March 2021 – Review of the PBS Authority Required (Written) listings: Tranche 2 (The Review)**

The PBAC considered the authority level of the following medicines for GIST: imatinib and sunitinib.

The PBAC did not recommend an amendment to the authority requirements for imatinib or sunitinib, noting that the recent increase in imatinib patient numbers demonstrated that the market was not yet stable. The PBAC recommended that DUSC review the utilisation of the entire GIST market in 12 months’ time and noted utilisation data for the adjuvant GIST indication and metastatic GIST indication should be analysed separately.

For further details refer to the [Outcome Statement](https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2021-03/march-2021-pbac-web-outcomes.pdf) from the March 2021 PBAC meeting.

**July 2021 - ripretinib**

The PBAC recommended the Authority Required (immediate/real-time assessment) listing of ripretinib for treatment of advanced GIST. The resubmission provided a revised price and financial estimates in response to previous concerns raised by the PBAC. In addition, the resubmission included updated survival data from the key clinical trial. The PBAC considered the revised incremental cost-effectiveness ratio (ICER) was high but likely overestimated due to the survival benefit being underestimated as a result of using the less favourable earlier data cut and the control group crossing over to receive treatment with ripretinib. The PBAC considered the ICER was acceptable in the context of advanced GIST being a rare cancer with an unmet need for effective third line treatment. In addition, the PBAC considered the revised financial estimates addressed previous concerns.

For further details refer to the [Public Summary Document](https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2021-07/ripretinib-tablet-50-mg-qinlock) from the July 2021 PBAC meeting.

## Previous reviews by the DUSC

At its October 2013 meeting, DUSC reviewed imatinib for the adjuvant treatment of GIST. In the first year of listing, the number of patients treated with imatinib was higher than estimated. DUSC considered that this could be due to an underestimation of the prevalent population. However, the number of prescriptions was lower than estimated. DUSC considered that this was partly due to grandfathered patients transferring from non-PBS subsidised imatinib to PBS subsided imatinib for part of their 12 months of therapy, thereby adding to the patient number but receiving fewer PBS prescriptions. DUSC advised to undertake another utilisation analysis of imatinib 24 months after the extension to listing to permit three years of treatment was implemented.

At its February 2017 meeting, DUSC reviewed the utilisation of imatinib for the adjuvant treatment of GIST. In the first two years from the extension to the PBS listing on 1 December 2013, 449 patients were supplied imatinib for the adjuvant treatment of GIST. This was similar to the number of patients estimated by the submission. However, there were fewer prescriptions than predicted, which may have been due to discontinuation from side effects or treatment failures. The total net expenditure was higher than expected, likely due to the higher than predicted average daily dose.

For details of the DUSC consideration of imatinib for GIST refer to the [Public Release Document](https://www.pbs.gov.au/info/industry/listing/participants/public-release-docs/2017-02/imatinib-gastrointestinal-stromal-tumour-feb-2017) from the February 2017 DUSC meeting.

# Methods

Data extracted from the PBS claims database maintained by the Department of Health, Disability and Ageing and processed by Services Australia were used for the analyses. Prescription data were extracted from 1 January 2004 up to and including 30 September 2024.

Prescription data were used to determine the prescription and patient counts by quarter and year of supply. An initiating patient was defined based on first date of supply of the respective drug. Analyses of adjuvant and metastatic GIST were based on the corresponding item code for each indication. Additional analyses of form and strength and age and gender distribution were also conducted.

A drug sequence analysis was conducted to examine the pattern of metastatic GIST utilisation in patients. A cohort was selected from patients who initiated treatment with GIST medicines prior to the PBS listing of ripretinib (1 December 2021) and followed to analysis end date, 30 September 2024. The first prescribed drug was recorded and if patients were subsequently supplied other drugs, these were noted to form the patient’s drug chronological sequence.

As this analysis uses date of supply prescription data, there may be small differences compared with publicly available Services Australia Medicare date of processing data.[[6]](#footnote-7) The publicly available Services Australia Medicare data only includes subsidised R/PBS prescriptions with prescriptions under the patient co-payment not included. The Services Australia Medicare data used in this report includes under co-payment prescriptions from 1 April 2012.

# Results

## Analysis of drug utilisation

### Overall utilisation

Table 9: Utilisation of GIST medicines by calendar year

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **2018** | **2019** | **2020** | **2021** | **2022** | **2023** |
| Patients treated  | 895 | 946 | 997 | 1,038 | 1,371 | 1,431 |
| Prescriptions supplied  | 7,619 | 7,437 | 6,829 | 7,050 | 9,406 | 9,940 |

Figure 1: Utilisation of PBS listed medicines for the treatment of GIST by supply quarter.

Table 9 and Figure 1 shows the overall utilisation of GIST medicines. Prior to 2022Q2, there were approximately 670 patients treated per quarter. Following 2022Q2, the number of patients treated increased to approximately 940 patients per quarter.

Figure 2: Patients treated by GIST type and supply quarter.

Figure 2 shows the number of patients treated for adjuvant and metastatic GIST. Overall, there were a greater number of patients treated for metastatic GIST compared to adjuvant GIST. There were larger increases in the number of initiating patients treated for adjuvant GIST compared to metastatic GIST, particularly in 2019Q3 and 2022Q2. These increases in the number of patients may be due to the change in the initial listing for imatinib to Authority Required (Telephone) in September 2019 and the capsule form of imatinib being listed in November 2021.

Figure 3: Number of prescriptions supplied by GIST type and supply quarter

Figure 3 shows the number of prescriptions supplied by GIST type. Overall, a greater number of prescriptions for metastatic GIST have been supplied compared to adjuvant GIST.

Figure 4: Metastatic GIST patients treated by drug and supply quarter.

Figure 4 shows the number of metastatic GIST patients treated by drug. The number of patients treated with sunitinib and ripretinib appear to be relatively stable, with approximately 60 and 43 patients treated per supply quarter.

Figures 5 and 6 show the number of prescriptions supplied for imatinib for adjuvant and metastatic GIST by form and strength. Capsules accounted for a greater proportion of imatinib prescriptions supplied for adjuvant GIST compared to metastatic GIST.

Figure 5: Number of imatinib for adjuvant GIST prescriptions supplied by form and strength and supply quarter

Figure 6: Number of imatinib prescriptions supplied for metastatic GIST by form and strength and supply quarter.

### Utilisation by relevant sub-populations/regions or patient level analysis

Figures 7 and 8 show the age and gender distribution of initiating GIST patients. Across both adjuvant and metastatic patients, 70-74 years old was the most common initiating age group. Males were more commonly treated compared to females in both adjuvant and metastatic GIST.

Figure 7: Age and gender distribution of initiating adjuvant GIST patients

Figure 8: Age and gender distribution of initiating metastatic GIST patients.

Table 10: Sequence analysis of PBS listed medicines for metastatic GIST

|  |  |  |
| --- | --- | --- |
| **Sequence**  | **Patients**  | **Percent**  |
| IMATINIB | 2,098 | 75% |
| IMATINIB → SUNTINIB | 446 | 16% |
| SUNTINIB | 133 | 5% |
| IMATINIB → SUNTINIB → RIPRETINIB  | 103 | 4% |
| Other sequences  | 23 | 1% |

Table 10 shows the sequence pathway of metastatic GIST patients. Most patients (75%) have initiated and remained on imatinib therapy. This was followed by 16% of patients who have switched from imatinib to sunitinib. There were 4% of patients who transitioned to from third-line ripretinib therapy.

# Discussion

The utilisation of medicines for the treatment of GIST has been stabilising from the second quarter of 2022. Overall, there has been greater utilisation of medicines for the treatment of metastatic GIST compared to adjuvant GIST. However, there has been a larger percentage increase in the utilisation adjuvant GIST medicines compared to metastatic GIST medicines. The increase in utilisation may be due to the listing of imatinib capsules in November 2021.

Given its place as first-line therapy for the treatment of metastatic GIST, imatinib accounted for the majority of metastatic GIST utilisation. This was followed by sunitinib and ripretinib, as the second and later liner therapies, respectively. Although the PBS restriction (third-line setting) of ripretinib is wider than its TGA indication (fourth-line setting), only a small number of patients have transitioned to later line therapy with ripretinib which may relate to it being subjected to black triangle monitoring.

# DUSC consideration

DUSC noted the listings for adjuvant and metastatic GIST had stabilised since 2022Q2.

DUSC noted the number of initiating patients in the metastatic setting had remained relatively stable, whereas increases in the number of initiating patients in the adjuvant setting were observed in 2020Q1 and in 2021Q4. DUSC noted the capsule form of imatinib was listed in November 2021 and since listing had accounted for greater utilisation in the adjuvant setting compared to the metastatic setting. DUSC noted the size of imatinib tablets and considered the difficulties patients may have in swallowing them. DUSC noted that prior to the listing of the capsule form, imatinib tablets was the only therapy available in the adjuvant setting and considered that patients would have initiated treatment given it was the only therapy available. DUSC noted imatinib was listed for other indications and considered the potential for leakage. DUSC noted following the increase in the adjuvant setting, the number of patients treated with imatinib had stabilised in both the adjuvant and metastatic settings.

# DUSC actions

DUSC requested that the report be provided to the PBAC for consideration.

# Context for analysis

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

# Sponsors’ comments

The sponsors did not have comments.

# Disclaimer

The information provided in this report does not constitute medical advice and is not intended to take the place of professional medical advice or care. It is not intended to define what constitutes reasonable, appropriate or best care for any individual for any given health issue. The information should not be used as a substitute for the judgement and skill of a medical practitioner.

The Department of Health, Disability and Ageing has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up-to-date when it was considered by the Drug Utilisation Sub-committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

To the extent provided by law, the Department of Health, Disability and Ageing, makes no warranties or representations as to accuracy or completeness of information contained in this report.

To the fullest extent permitted by law, neither the Department of Health, Disability and Ageing nor any Department of Health, Disability and Ageing employee is liable for any liability, loss, claim, damage, expense, injury or personal injury (including death), whether direct or indirect (including consequential loss and loss of profits) and however incurred (including in tort), caused or contributed to by any person’s use or misuse of the information available from this report or contained on any third party website referred to in this report.

# Appendices

## Appendix A: Brand and manufacturer details of PBS listed GIST medicines (as at December 2024)

**Adjuvant GIST**

|  |  |
| --- | --- |
| **Item codes** | **Brand and manufacturer** |
| imatinib 100 mg tablet (5443L, 11784F)imatinib 400 mg tablet (5444M, 11788K) | Glivec®: Novartis Pharmaceuticals Australia Pty LimitedGilmat®: Pharmacor Pty LimitedImatinib RBX®: Sun Pharma ANZ Pty LtdImatinib – TEVA®: Teva Pharma Australia Pty Ltd Imanib®: Alphapharm Pty Ltd Imatinib Sandoz: Sandoz Pty Ltd |
| imatinib 100 mg capsule (12709X, 12722N) | Imatinib-APOTEX®: Apotex Pty Ltd IMATINIB-DRLA®: Dr Reddy's Laboratories (Australia) Pty Ltd, ARX-imatinib®: Arrotex Pharmaceuticals Pty Ltd |
| imatinib 400 mg capsule (12681K, 12711B) | Imatinib-APOTEX®: Apotex Pty Ltd IMATINIB-DRLA®: Dr Reddy's Laboratories (Australia) Pty Ltd, ARX-imatinib®: Arrotex Pharmaceuticals Pty LtdImatinib GH®: Generic Health Pty Ltd |

**Metastatic GIST**

| **Item codes** | **Brand and manufacturer** |
| --- | --- |
| imatinib 100 mg tablet (9111M, 11787J)imatinib 400 mg tablet (9112N, 11778X) | Glivec®: Novartis Pharmaceuticals Australia Pty LimitedGilmat®: Pharmacor Pty LimitedImatinib RBX®: Sun Pharma ANZ Pty LtdImatinib – TEVA®: Teva Pharma Australia Pty Ltd Imanib®: Alphapharm Pty Ltd Imatinib Sandoz: Sandoz Pty Ltd |
| Imatinib 600 mg tablet (12926H, 12919Y) | Imatab®Juno Pharmaceuticals Pty Ltd |
| imatinib 100 mg capsule (12709X, 12722N) | Imatinib-APOTEX®: Apotex Pty Ltd IMATINIB-DRLA®: Dr Reddy's Laboratories (Australia) Pty LtdARX-imatinib®: Arrotex Pharmaceuticals Pty Ltd |
| imatinib 400 mg capsule (12754G, 12723P) | Imatinib-APOTEX®: Apotex Pty Ltd IMATINIB-DRLA®: Dr Reddy's Laboratories (Australia) Pty LtdARX-imatinib®: Arrotex Pharmaceuticals Pty LtdImatinib GH®: Generic Health Pty Ltd |
| sunitinib 12.5 mg capsule (9488J, 11266Y) | Sunitinib MSN®: Cipla Australia Pty LtdSunitinib Sandoz®: Sandoz Pty LtdSuntent® : Pfizer Australia Pty Ltd |
| sunitinib 25 mg capsule, 28 (9489K,11253G)sunitinib 37.5 mg capsule (10503T, 11256K)sunitinib 50 mg capsule (9490L, 11250D) | ARX-Sunitnib®: Arrotex Pharmaceuticals Pty LtdSunitinib MSN®: Cipla Australia Pty LtdSunitinib Sandoz®: Sandoz Pty LtdSuntent®: Pfizer Australia Pty Ltd |
| ripretinib 50 mg tablet (12764T) | Qinlock®: Specialised Therapeutics Pm Pty Ltd |

1. GI Cancer Institute Australia. Gastro-intestinal Stromal Tumour (GIST). Accessed from:  <https://gicancer.org.au/cancer/gastro-intestinal-stromal-tumour-gist/#cancer-explanation> [↑](#footnote-ref-2)
2. Glivec (imatinib). Australian Product Information. Macquarie Park: Novartis Pharmaceuticals Australia Pty Ltd. Approved 13 August 2001, updated 27 July 2022. Available from < https://www.tga.gov.au/product-information-pi.> [↑](#footnote-ref-3)
3. Sutent (sunitnib). Australian Product Information. Sydney: Pfizer Australia Pty Ltd. Approved14 September 2006, updated 31 October 2019. Available from < https://www.tga.gov.au/product-information-pi.> [↑](#footnote-ref-4)
4. Qinlock (ripretinib). Australian Product Information. Kew: Specialised Therapeutics PM Pty Ltd. Approved 13 July 2020, updated 1 July 2024. Available from < https://www.tga.gov.au/product-information-pi.> [↑](#footnote-ref-5)
5. Department of Health and Aged Care. PBS News: 1 September 2022 updates as part of the Digital Transformation of Authority Required (Written) listings. Accessed from: https://www.pbs.gov.au/info/news/2022/08/1-september-2022-updates-as-part-of-the-digitaltransformation [↑](#footnote-ref-6)
6. PBS statistics. Australian Government Services Australia. Canberra. Available from <<http://www.medicareaustralia.gov.au/provider/pbs/stats.jsp>>. [↑](#footnote-ref-7)