Australian Government

Department of Health

Consultation Survey on MSAC Application 1760

DPYD genotyping to predict fluoropyrimidine-induced toxicity

MSAC welcomes input on MSAC applications for public funding from individuals, organisations representing health professionals or consumers and/or carers, and from other stakeholders. Please use this template to prepare your input. You may also attach additional information if you consider it may be useful in informing MSAC and its sub-committees.

Sharing consultation input

Submitted consultation input will be routinely shared with the applicant and with MSAC and its sub-committees.

- The applicant will receive a summary of comments from individuals, with the individual's name and other identifying information removed.
- MSAC and its sub-committees will receive both the summary and copies of the comments, with the name of the individual and other identifying information removed.
- Consultation input from groups or organisations will be provided in a complete form to both the applicant and to MSAC and its sub-committees.

Consultation input may also be shared with HTA Assessment Groups from time to time to inform their reports to MSAC or with state and territory health representatives where the application is for a service to be delivered through public hospitals. Please do not include information in your input that you do not want shared as outlined above. In addition, to protect privacy, do not include identifying personal (e.g., name) or sensitive (e.g., medical history) information about third parties, such as medical professionals or friends/relatives.

How consultation input is used

MSAC and its sub-committees consider consultation input when appraising an application, including to better understand the potential impact of the proposed medical technology/service on consumers, carers, and health professionals. A summary of consultation input will be included in the Public Summary Document (PSD) published on the MSAC website once MSAC has completed its appraisal. The PSD may also cite input from groups/organisations, including the name of the organisation. As such, organisations should not include information or opinions in their consultation input that they would not wish to see in the public domain.

Consultation deadlines. Please ensure that your consultation input is submitted by the pre-PASC or pre-MSAC consultation deadline for this application. Consultation deadlines for each PASC and MSAC meeting are listed in the PASC, ESC, MSAC key dates available on the MSAC website. They are also published in the MSAC Bulletin. Consultation input received after the respective deadlines may not be considered.

For further information on the MSAC consultation process please refer to the MSAC Website or contact the Consumer Evidence and Engagement Unit on email: commentsMSAC@health.gov.au.
Thank you for taking the time to provide consultation input. Please return your completed survey to:

Email: commentsMSAC@health.gov.au

Mail: MSAC Secretariat,
MDP 960, GPO Box 9848,
ACT 2601.

PART 1 – PERSONAL AND ORGANISATIONAL INFORMATION

1. Respondent details

Name: Jerry Yik (Head of Policy and Advocacy)

Email: jyik@shpa.org.au

Phone No: 0424 087 068

2. Is the feedback being provided on an individual basis or by a collective group?

☐ Individual
☒ Collective Group

If an individual, specify the name of the organisation you work for

N/A

If a collective group, specify the name of the group

The Society of Hospital Pharmacists of Australia (SHPA)

3. How would you best identify yourself?

☐ General Practitioner
☐ Specialist
☐ Researcher
☐ Consumer
☐ Care giver
☒ Other

If other, please specify

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

PART 2 – CLINICAL NEED AND PUBLIC HEALTH SIGNIFICANCE

4. Describe your experience with the medical condition (disease) and/or proposed intervention and/or service relating to the application summary

SHPA convenes an Oncology and Haematology Specialty Practice Group, comprising of a network of specialist pharmacists who work to optimise best practice cancer care for oncology and haematology patients in inpatient, outpatient, ambulatory care or primary care settings where patients of any age receive cancer services and pharmacy services. These members are key workers in the provision of safe and quality cancer care. Oncology pharmacists play a critical role in safe chemotherapy prescribing, including the prescribing of fluoropyrimidine (FP) based treatments for cancer patients around the nation.

SHPA also publishes the ***Standard of practice in oncology and haematology for pharmacy services*** and has an Oncology and Haematology Advanced Training Residency program to train pharmacists to become specialist pharmacists in oncology and haematology.

Fluoropyrimidine (FP) based treatments are very commonly used, especially in the treatment of solid tumours. In most cases, FPs are not urgently required treatments, and the turnaround time on conducing and processing DPYD genotyping tests to predict toxicity would be acceptable prior to commencing therapy, particularly as it can prevent life-threatening toxicity.

There have been previous cases where the absence of DPYD genotyping prior to FP treatment initiation have contributed to the following deaths:

- Court reference: COR 2015 4937 – this 2015 case details of severe neutropenic sepsis and multi-organ failure secondary to severe mucositis and probable DPD deficiency in the setting capecitabine therapy for the treatment of T3 rectal carcinoma.
- Court reference: COR 2018 5623 – 2018 case description for probable death due to neutropenic sepsis leading to multi-organ failure in the setting of rectal cancer T2N0M0 post neoadjuvant chemotherapy and radiotherapy, in the setting of capecitabine toxicity and lack of availability of uridine triacetate.

Both cases highlight the critical role of DPYD genotyping in reducing patient harm due to FP toxicity and recommend that the testing for DPD deficiency should be made standard of care for patients proposed to be commenced on FP based treatments

5. What do you see as the benefit(s) of the proposed medical service, in particular for the person involved and/or their family and carers?

In individuals with complete absence of DPD function, exposure to FPs can be fatal, and intermediate or poor metabolisers of FP are also at risk of potentially life-threatening toxicity. DPYD testing can be lifesaving for these patients if they are considered for commencement of FP treatment, reducing both mortality and morbidity rates. DPYD genotyping will also contribute to improvement in health system capacity through reduced resources required to manage potential toxicity in DPD deficient individuals.

SHPA has previously supported the Royal College of Pathologists of Australasia (RCPA) in their application for DPYD genotyping to predict FP induced toxicity. This is particularly in response to the concerns around the lack of availability of uridine triacetate (Vistogard) in Australia, which is used in FP overdose or overexposure. In a time-critical scenario such as a severe FP toxicity, sourcing uridine triacetate currently presents with financial and logistical challenges. Therefore, the public funding of DPYD testing to determine DPD enzyme deficiency prior to FP treatment initiation is essential in reducing harm for individuals initiating FP based treatment.

6. What do you see as the disadvantage(s) of the proposed medical service, in particular for the person involved and/or their family and carers?

Potential disadvantage of DPYD genotyping may include delays in initiating FP treatment, particularly in areas where timely testing is not feasible. However, if the proposed service is to become a publicly funded intervention, testing will become more available and widely accessible, which will address the issues surrounding timely testing.

7. What other benefits can you see from having this intervention publically funded?

Public funding of DPYD genotyping will ensure equity of access to all Australians receiving. This is especially useful for rural patients where upfront hospital testing may have cost and geographical barriers.

8. What other services do you believe need to be delivered before or after this intervention, e.g. Dietician, Pathology etc?

Oncology review to interpret the outcomes of DPYD genotyping will be required to allow clinicians to adjust treatment plans as appropriate.

PART 3 – INDICATION(S) FOR THE PROPOSED MEDICAL SERVICE AND CLINICAL CLAIM

9. Do you agree or disagree with the proposed population(s) for the proposed medical service?

- ☐ Strongly Agree
- ☒ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Specify why or why not:

The proposed population description in the application summary states, "patients with solid organ tumours, including colorectal upper gastrointestinal, breast and head and neck cancers, who are undergoing standard chemotherapy treatment with fluoropyrimidines (FP)".

This population should not be limited to individuals with solid tumours only, but capture all adults undergoing FP treatment for malignancy.

10. Have all the associated interventions been adequately captured in the application summary?

- ☒ Yes
- ☐ No

Please explain:

The four listed DPYD genotyping tests are in line with current clinical practice and are already tested by the Melbourne Pathology group.

11. Do you agree or disagree that the comparator(s) to the proposed medical service?

- ☒ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Please explain:

The current alternative to DYPD genotyping is appropriately described in the application summary.

12. Do you agree or disagree with the clinical claim made for the proposed medical service?

- ☐ Strongly Agree
- ☒ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Specify why or why not:

DPYD genotyping will allow clinicians to adjust doses of FP treatment or consider alternative treatment, rather than cessation of treatment as described in the application summary. Clinicians will be able to use alternative chemotherapy protocols depending on the severity of the predicted toxicity for the individuals under their care.

PART 4 – COST INFORMATION FOR THE PROPOSED MEDICAL SERVICE

13. **Do you agree with the proposed service descriptor?**

- ☐ Strongly Agree
- ☒ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Specify why or why not:

The proposed service descriptor should include the word 'systemically' in place of 'either orally or intravenously' to ensure all methods of FP administration are included.

14. **Do you agree with the proposed service fee?**

- ☐ Strongly Agree
- ☒ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Specify why or why not:

SHPA has no specific opinion on the cost of the proposed service.

PART 5 – ADDITIONAL COMMENTS

15. Do you have any additional comments on the proposed intervention and/or medical condition (disease) relating to the proposed medical service?

Nil further comments.

16. Do you have any comments on this feedback survey? Please provide comments or suggestions on how this process could be improved.

Nil further comments.

Again, thank you for taking the time to provide valuable feedback.