11.02 NINTEDANIB, Capsule 100 mg Capsule 150 mg Ofev®, Boehringer Ingelheim Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested the PBAC to revise the subsidisation caps for nintedanib for Idiopathic Pulmonary Fibrosis (IPF) and Chronic Fibrosing Interstitial Lung Disease with a progressive phenotype PF-ILD.

1.2 The sponsor proposed that the subsidisation caps for IPF and PF-ILD be combined for the remaining duration of the PF-ILD deed.

2 Requested listing

2.1 The submission proposed no changes to the existing listing. Therefore, the full restrictions have not been included here.

3 Background

Previous PBAC consideration

3.1 Nintedanib was previously considered for treatment of IPF by the PBAC in March 2015 and November 2015, and was recommended at its November 2016 meeting. Nintedanib was previously considered for treatment of PF-ILD by the PBAC in March 2021, and it was recommended by the PBAC at its September 2021 meeting. Nintedanib in combination with docetaxel was previously considered by the PBAC for second line treatment of non-small cell lung cancer (NSCLC) in March 2015 and March 2016 and has not been recommended by the PBAC.

3.2 In November 2016, the PBAC recommended nintedanib for the IPF population, and recommended a risk sharing arrangement (RSA) which would cap Government financial expenditure based on the submission's estimates for treated patients and adjusted for the continuation rule. The PBAC recommended a 100% rebate should apply to any Government expenditure beyond the financial cap. The PBAC further recommended that any other drugs recommended for the treatment of IPF in the future should be included within the same financial caps.

3.3 Following a deferred outcome at the November 2016 PBAC meeting, pirfenidone was recommended on a cost minimisation basis compared to nintedanib at the December 2016 PBAC meeting. The PBAC recalled that nintedanib was recommended for IPF with a risk sharing arrangement which would cap Government financial

expenditure based on the nintedanib submission's financial estimates and a % rebate to any Government expenditure beyond the financial cap. The PBAC recommended that pirfenidone should be included within the same financial caps.

3.4 In July 2019, the sponsor requested an increase in the financial caps. The submission claimed that the estimates used in determining the caps were based on uptake rates specific for nintedanib. The submission proposed that the "class subsidisation caps" that had been presented in the sponsor's submission to the November 2016 meeting should be used for Years 2 to 5 of the Deed. The PBAC advised that its previous recommendation about the RSA subsidisation caps for nintedanib for the treatment of IPF should not be amended. The PBAC noted the submission's reference to the different financial models that were presented to PBAC at its November 2016 meeting – a "class" model and a nintedanib-specific model that differed in rate of uptake. The submission claimed that using the nintedanib-specific model (which was used as the basis for the RSA caps) leads to an underestimation of the caps across the two therapies (nintedanib and pirfenidone). However, the PBAC noted the previous DUSC advice that class subsidisation caps would be expected to be consistent with nintedanib subsidisation caps in the context of no other available treatments.

3.5 In September 2021, the PBAC recommended nintedanib for the PF-ILD population, and recommended an RSA for the PF-ILD population. The PBAC noted the resubmission provided financial estimates which included revised uptake rates, a revised prevalence rate for PF-ILD and amended dose weightings for the 150 mg versus 100 mg dose. The PBAC considered the revised financial estimates resulted in a more reasonable estimate of utilisation and largely addressed the concerns raised by the Committee in March 2021. The PBAC considered that while the revised financial estimates and RSA did not account for potential overlap between ILD and PF-ILD, the proposed RSA would be adequate to mitigate the risk of expenditure associated with use outside the eligible population. The PBAC advised that a rebate of at least % above the RSA caps should apply. The PBAC considered that the requirement for diagnosis by a multidisciplinary team, and the clinical criterion specifying that the patient must not have ILD due to IPF within the restriction should reduce the risk of IPF patients accessing nintedanib through the listing for PF-ILD.

Current RSA and expenditure

3.6 Nintedanib was PBS-listed for IPF on 1 May 2017, and for PF-ILD on 1 May 2022. The two listings are subject to separate Deeds with subsidisation caps.

3.7 Pirfenidone was added to the IPF RSA when it was PBS listed, however the originator brand of pirfenidone was delisted 1 October 2023 and it is now listed in the F2 formulary. The submission stated that the sponsor understands pirfenidone is no longer subject to the IPF RSA. The Department has advised the sponsor that under the current Deed, [redacted].

3.8 On 1 June 2022, the nominal Term of the Deed for IPF lapsed beyond its original five years, and the Continued Operations clause came into effect (clause 7 of the Deed).

Since then, the Year 5 subsidisation cap ($[redacted]) has applied to each year of expenditure, and will apply until a new Deed is negotiated.

3.9 The submission presented the current IPF and PF-ILD caps as shown in Table 1.

Table 1: Proposal for combined IPF and PF-ILD subsidisation caps*

	2023-24	2024-25	2025-26	2026-27
Current IPF subsidisation caps($)	[redacted]	[redacted]	[redacted]	[redacted]
Current PF-ILD subsidisation caps ($)	[redacted]	[redacted]	[redacted]	[redacted]
Proposal for combined IPF and PF-ILD subsidisation caps ($)	[redacted]	[redacted]	[redacted]	[redacted]

Source: Submission Table 1, p1.
Abbreviations: IPF, idiopathic pulmonary fibrosis; PF-ILD, chronic fibrosing interstitial lung disease with a progressive phenotype
Note: Each year commences on 1 May
* Nintedanib has a special pricing arrangement

3.10 As Year 7 of the Current IPF Deed (Period from 1 May 2023 to 30 April 2024) has already passed, changes to this period cannot be made retrospectively.

3.11 The submission presented the Commonwealth payments and rebates for IPF since the commencement of the Deed on 1 May 2017 as shown in Table 2. Commonwealth payment for nintedanib for IPF was added.

Table 2: Overview of Commonwealth payment and nintedanib rebates for IPF

	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23
Total IPF Commonwealth payment ($)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Nintedanib Commonwealth payment ($)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Nintedanib market share (%)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Cap threshold ($)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Nintedanib rebate for IPF($)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Source: Submission Table 2, p3. Department of Health and Aged Care.
Abbreviations: IPF, idiopathic pulmonary fibrosis
Note: Each year commences on 1 May.

3.12 The submission did not include the Commonwealth payments for PF-ILD. In the first year of the Deed (May 2022 to April 2023) the Total Commonwealth payment was $[redacted], reaching 25% of the subsidisation cap of $[redacted], indicating that the current PF-ILD caps are significantly overestimated. It is likely that combined nintedanib and pirfenidone IPF and PF-ILD expenditure would be below the submission's proposed combined caps. If the two RSAs are combined, the overestimate of PF-ILD would effectively be subsidising IPF, and there is a risk that the RSA would no longer be effective.

Negotiation of new RSA

3.13 The submission presented the subsidisation caps proposed by the sponsor and the Department (Figure 1).

Figure 1: Submission's overview of latest nintedanib IPF subsidisation caps proposed by the Department and Boehringer Ingelheim

Source: Submission Figure 1, page 4

3.14 The submission stated the Department's proposal for nintedanib subsidisation caps effectively halves the original subsidisation caps for IPF and then applied annual growth of %.

3.15 This statement and Figure 1 should be considered in the context for the Department's proposed caps. The Department's proposal for a new nintedanib IPF Deed was based on expenditure for nintedanib only, rather than both nintedanib and pirfenidone. The "halving" of the caps reflects that the market share of nintedanib is approximately 50% and expenditure for pirfenidone (the other 50% of the market) would no longer contribute to expenditure against nintedanib-only caps.

3.16 The submission stated the sponsor's latest proposal for nintedanib subsidisation caps to the Department was to apply annual growth of % to the Year 5 subsidisation cap from the original Deed ($). This was not accepted as it did not account for the reduction in price that applied to pirfenidone when the first new brand was listed and therefore inflates costs of the whole IPF market.

3.17 The PBAC noted that the sponsor was provided with options for ongoing arrangements:

a)

b) [redacted]

c) [redacted]

3.18 The sponsor continued to propose new subsidisation caps, the most recent proposal was 3% growth per year from 2022-2023, with an understanding that the higher cap in 2022-2023 would not be retrospectively applied to the reimbursement calculations. This proposal did not mention whether pirfenidone expenditure would be included for the calculation of market share, and did not consider the price reductions applied to pirfenidone.

3.19 Subsidisation cap proposals from the Department and the sponsor are summarised in Table 3.

Table 3: Subsidisation cap proposals

	May - April	Current IPF Caps ($)	Department proposal nintedanib only 7 & 15 March 2024 ($)	Department proposal nintedanib and pirfenidone 8 April 2024 ($)	Sponsor proposal (correspondence 15 April 2024) ($)	Sponsor Proposal (submission IPF and PF-ILD combined) ($)
Year 1	2017 - 2018	[redacted]				
Year 2	2018 - 2019	[redacted]				
Year 3	2019 - 2020	[redacted]				
Year 4	2020 - 2021	[redacted]				
Year 5	2021 - 2022	[redacted]				
Year 6	2022 - 2023	[redacted]				
Year 7/ New Year 1	2023 - 2024	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Year 8/ New Year 2	2024 - 2025	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Year 9/ New Year 3	2025 - 2026	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Year 10/ New Year 4	2026 - 2027	[redacted]	[redacted]		[redacted]	[redacted]
Year 11/ New Year 5	2027 - 2028		[redacted]			

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The PBAC noted and welcomed the input from organisations (1) via the Consumer Comments facility on the PBS website. The comments described a range of benefits of treatment with nintedanib from patients receiving it through the PBS, including fewer

side effects such as nausea and vomiting compared to treatment with pirfenidone and financial difficulties patients would experience if it was not PBS listed.

Submission request

4.3 The submission's request was based on the arguments that the current subsidisation caps for IPF are based on underestimated nintedanib uptake rates and maximum uptake has not yet been reached, and that nintedanib uptake under the IPF PBS item code has increased at a faster rate than under the PF-ILD PBS item code, due to:

a) Patients who are first prescribed nintedanib under the IPF PBS item code are restricted from transitioning to the PF-ILD PBS item code if the cause of disease is later revised.

b) Some healthcare professionals are treating IPF and PF-ILD as a single diagnostic entity given the similarities in the clinical behaviour, pathogenic pathway, and efficacy of antifibrotic therapy.

c) There is potential for pharmacists to misclassify the IPF and PF-ILD PBS item codes due to their similarities, with the PBS item code being the sole distinguishing factor in dispensing software.

Uptake rates

4.4 The submission claimed that the current subsidisation caps for IPF are based on underestimated nintedanib uptake rates and maximum uptake has not yet been reached.

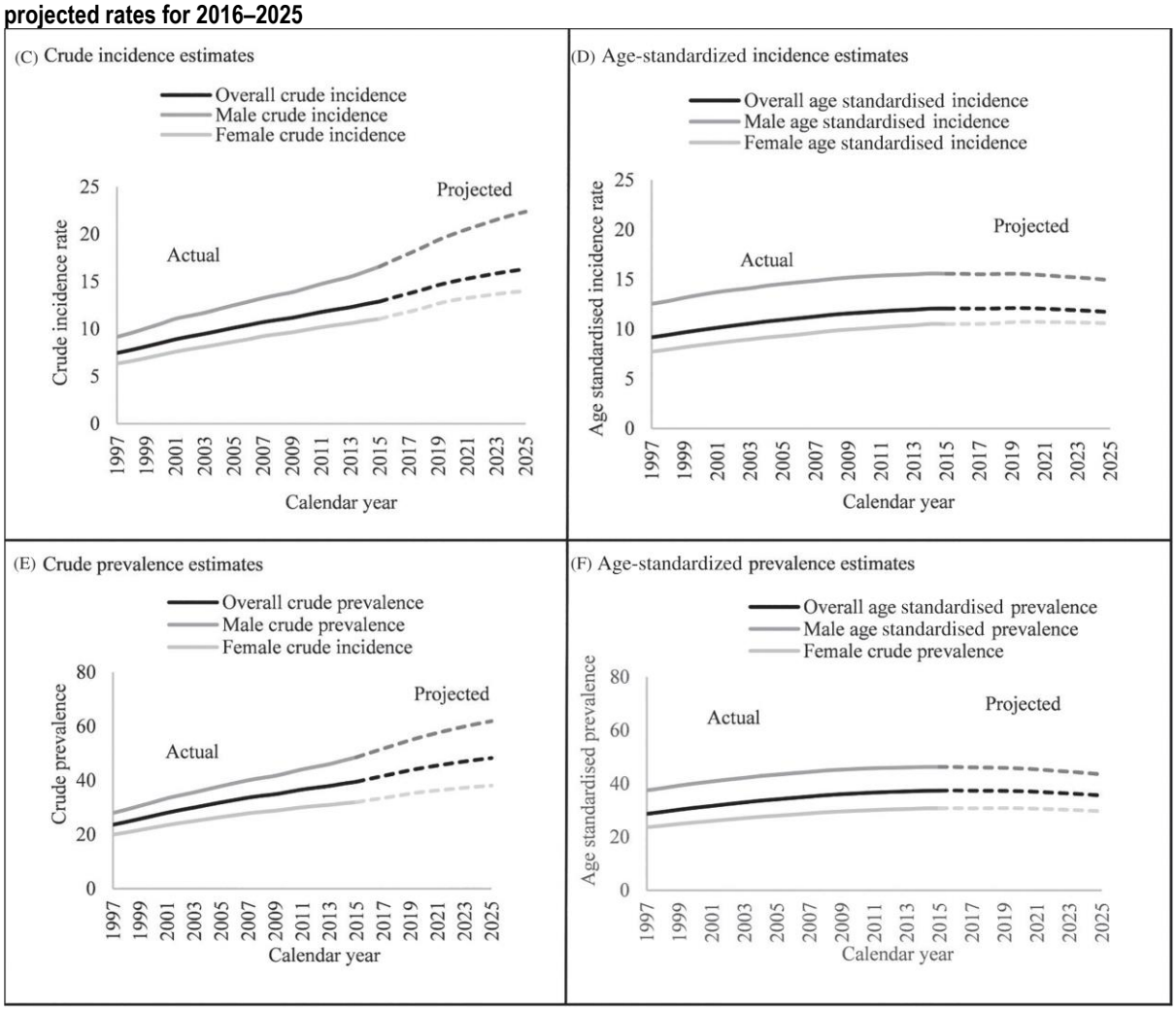
4.5 The submission claimed that the maximum uptake of nintedanib has not been reached, and argued that the uptake rates applied in the base case financial analysis considered the scenario where nintedanib was the only medicine subsidised on the PBS given both nintedanib and pirfenidone were previously rejected multiple times. The PBAC previously recommended nintedanib and pirfenidone should be included within the same financial caps.

4.6 The submission quoted the DUSC analysis of IPF from 2020 as, "at the time of its consideration of the November 2016 nintedanib submission, DUSC considered the estimates presented in the resubmission to be underestimated. The predicted versus actual review of the nintedanib November 2016 estimates showed that the number of patients treated for IPF in the first two years of listing were underestimated" (Item 7.2 DUSC February 2020). The report also found that the number of supplied prescriptions was overestimated in the first year of listing, and approximately correct in the second year of listing.

4.7 The estimated prevalence of IPF used in the base estimates was 14.4/100,000. DUSC noted that the resubmission (November 2016) selected studies where the definition of IPF was consistent with the requested restriction. Therefore, DUSC considered that 14.4/100,000 represented the restriction prevalence rather than the population prevalence of IPF. The first submission for nintedanib in March 2015, epidemiological

studies located by the submission reported prevalence rates that varied from 1.25/100,000 to 27.9/100,000. The current submission included a source (Cox 2021) which estimated the prevalence of IPF in Australia based on data from the Australian IPF Registry to be between 32.6 (crude) and 35.1 (age standardised) per 100,000 population. This source noted funding from the sponsor. The study used data from 1997 to 2015 to project incidence, prevalence and mortality to 2025. The submission did not provide a full literature review to explore other sources. The submission did not note whether this represents the restriction prevalence or the population prevalence.

Figure 2: Annual crude and age-standardised incidence and prevalence estimates for the period 1997–2015 and projected rates for 2016–2025



Source: Cox 2021, Figure 1.

Uptake under the IPF PBS item code compared to the PF-ILD PBS item code

4.8 The submission noted that patients who are first prescribed nintedanib under the IPF PBS item code are restricted from transitioning to the PF-ILD PBS item code if the cause of disease is later revised. The submission noted that IPF and PF-ILD share many of the same clinical criteria, however PF-ILD requires observation of disease

progression within two years prior to prescribing. The submission noted that many clinicians will correctly diagnose patients as IPF prior to being able to support a PF-ILD diagnosis, and the PBS treatment criteria does not allow for patients who begin treatment with nintedanib under the IPF code to subsequently receive treatment under the PF-ILD code. If PF-ILD had not been listed, it is likely these patients would still have been treated under the IPF PBS restriction.

4.9 The submission noted some healthcare professionals are treating IPF and PF-ILD as a single diagnostic entity given the similarities in the clinical behaviour, pathogenic pathway, and efficacy of antifibrotic therapy. The submission stated that distinguishing between IPF and PF-ILD is often inconsequential to the clinical course. As such, clinicians are 'lumping' these diseases together in diagnosis which may be contributing to the increasing uptake of nintedanib for IPF.

4.10 The submission noted there is potential for pharmacists to misclassify the IPF and PF-ILD PBS item codes due to their similarities, with the PBS item code being the sole distinguishing factor in dispensing software. The submission claimed 23% of patients classified as IPF, as per the approved authority application form, were dispensed nintedanib at least once under the PF-ILD PBS item code, and 50% of patients classified as PF-ILD have been dispensed nintedanib at least once under the IPF PBS item code. An analysis of the full PBS showed that at a prescription level there was more miscoding of IPF as PF-ILD than of PF-ILD as IPF, as suggested by the submission.

4.11 The submission used a 10% sample to estimate the percentage of patients being miscoded, i.e. patients supplied nintedanib with an authority for PF-ILD under an IPF PBS item code or vice versa. Of the patients supplied at least 12 months of nintedanib, the submission stated that 3% patients were prescribed nintedanib under both authority codes, and excluded these patients from further analyses. The submission stated that 23% of patients (110/470) classified as IPF by the approved authority application form, were dispensed nintedanib at least once under the PF-ILD PBS item code, and 50% of patients (130/260) classified as PF-ILD were dispensed nintedanib at least once under the IPF PBS item code. The submission therefore claimed that patients with a PF-ILD approved authority were more likely to receive nintedanib under the IPF PBS item code, as opposed to the other way around.

4.12 For the purposes of a Deed, the number or percentage of miscoded prescriptions is more useful to understand the impact of miscoding than counting miscoded patients. Presenting miscoding using patients supplied at least one miscoded prescription may overestimate the amount of miscoding.

4.13 An analysis of the full PBS data using prescriptions rather than patients supplied at least one miscoded prescription showed that since PF-ILD was PBS listed, more prescriptions with authorities for IPF were supplied under PF-ILD PBS item codes than prescriptions with authorities for PF-ILD supplied under IPF PBS item codes. In 2023, 1,301 (5%) prescriptions with PF-ILD authorities were supplied under IPF item codes,

and 1,964 (8%) prescriptions with IPF authorities were supplied under PF-ILD item codes.

Table 4: Prescriptions of nintedanib for IPF and PF-ILD in 2023

Year	Item code restriction	Authority restriction	Prescriptions	Percentage of item code restriction total	Percentage of total
2023	IPF	IPF (auth)	16,974	92%	69%
2023	IPF	Nil or not matched authorities	92	1%	0%
2023	IPF	PF-ILD (auth)	1,301	7%	5%
2023	IPF Total		18,367		
2023	PF-ILD	IPF (auth)	1,964	31%	8%
2023	PF-ILD	Nil or not matched authorities	26	0%	0%
2023	PF-ILD	PF-ILD (auth)	4,421	69%	18%
2023	PF-ILD Total		6,411		
2023	Total		24,778		

Source: Compiled during the evaluation.

4.14 Table 5 shows the number of prescriptions and authorities of nintedanib for IPF and PF-ILF by year. This indicates that if authorities were used rather than PBS item codes to determine the indication, the number of prescriptions for IPF would increase, even if non-matched prescriptions were excluded.

Table 5: Prescriptions of nintedanib for IPF and PF-ILD by year

	IPF			PF-ILD			
	Item code	Authority code	Difference	Item code	Authority code	Difference	Nil or not matched authorities
2017	2,313	2,271	-42			0	42
2018	7,211	7,138	-73			0	73
2019	10,182	10,102	-80			0	80
2020	12,461	12,400	-61			0	61
2021	14,309	14,211	-98			0	98
2022	15,624	16,044	420	2,067	1,546	-521	101
2023	18,367	18,938	571	6,411	5,722	-689	118
2024	9,947	9,991	44	3,768	3,678	-90	46

Source: Compiled during the evaluation.

4.15 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Estimated PBS usage and financial implications

4.16 The submission did not propose a change to the price of nintedanib.

4.17 The submission did not present estimates of use. Based on the proposed caps, the additional PBS/RPBS expenditure associated with the revised RSA versus the existing RSA is estimated to be $ million over 4 years.

Table 6: Estimated use and financial implications

		2023-24	2024-25	2025-26	2026-27
A	Predicted use of nintedanib and pirfenidone for IPF[a]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]
B	Predicted use of nintedanib for IPF (Ax0.5)	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
C	Predicted use of pirfenidone for IPF (Ax0.5x(1-34.57%))	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][2]
D	Nintedanib predicted market share (B/A)	60%	60%	60%	60%
E	Current IPF subsidisation caps	$[redacted]	$[redacted]	$[redacted]	$[redacted]
F	Predicted nintedanib reimbursements under current cap (A-E)	$[redacted]	$[redacted]	$[redacted]	$[redacted]
G	Predicted use of nintedanib for PF-ILD [b]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
H	Current nintedanib PF-ILD subsidisation caps	$[redacted]	$[redacted]	$[redacted]	$[redacted]
I	Predicted PF-ILD reimbursement	$[redacted]	$[redacted]	$[redacted]	$[redacted]
J	Predicted combined use (A+G)	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][5]
K	Submission's proposed combined caps (E+H)	$[redacted]	$[redacted]	$[redacted]	$[redacted]
L	Submission proposed predicted reimbursements	$[redacted]	$[redacted]	$[redacted]	$[redacted]
M	Estimated additional cost of combining caps (F-L)	$[redacted]	$[redacted]	$[redacted]	$[redacted]

Source: Calculated by the Department.

[a] Assuming a linear projection based on Commonwealth payments between May 2017 and April 2023.

[b] Assuming a logarithmic projection based on two years of Commonwealth payments.

The redacted values correspond to the following ranges:

1 $20 million to < $30 million

2 $10 million to < $20 million

3 $0 to < $10 million

4 $30 million to < $40 million

5 $40 million to < $50 million

4.18 The reimbursements for nintedanib for May 2023 to April 2024 have been estimated by the Department but are yet to be finalised:

Table 7: Nintedanib IPF Deed calculations

CAP Year	Drug Name	Deed Commonwealth Payment ($)	Market Share	Total Commonwealth Payment ($)	Cap Threshold ($)	% of cap reached
Year 1 May 2017 - April 2018	nintedanib	[redacted]	45.63%	[redacted]	[redacted]	[redacted]%
	pirfenidone		54.37%			
Year 2 May 2018 - April 2019	nintedanib		46.32%	[redacted]	[redacted]	[redacted]%
	pirfenidone		53.68%			
Year 3 May 2019 - April 2020	nintedanib		50.17%	[redacted]	[redacted]	[redacted]%
	pirfenidone		49.83%			
Year 4 May 2020 - April 2021	nintedanib		49.96%	[redacted]	[redacted]	[redacted]%
	pirfenidone		50.04%			
Year 5 May 2021 - April 2022	nintedanib		51.03%	[redacted]	[redacted]	[redacted]%
	pirfenidone		48.97%			
Year 6 May 2022 - April 2023	nintedanib		51.85%	[redacted]	[redacted]	[redacted]%
	pirfenidone		48.15%			
Year 7 May 2023 - April 2024*	nintedanib	[redacted]	54.41%	[redacted]	[redacted]	[redacted]%

*Year 7 is estimated, subject to change.

Table 8: Nintedanib PF-ILD Deed calculations

CAP Year	Drug Name	Total Commonwealth Payment ($)	Market Share	Cap Threshold 1 ($)	% of cap reached
Year 1 May 2022 - April 2023	nintedanib	[redacted]	100%	[redacted]	[redacted]%
Year 2 May 2023 - April 2024*	nintedanib	[redacted]	100%	[redacted]	[redacted]%

*Year 2 is estimated, subject to change.

5 PBAC Outcome

5.1 The PBAC did not recommend that the risk sharing arrangement (RSA) subsidisation caps for nintedanib for IPF and PF-ILD be combined. The PBAC advised that the evidence provided by the submission did not sufficiently justify the requested combination of the subsidisation caps and considered that the proposed arrangements would not adequately manage the risks originally identified in relation to the nintedanib listings. The PBAC considered that the current RSA for IPF has been working as intended to manage the uncertainty around the original financial estimates and cost-effectiveness for IPF, while the financial estimates for PF-ILD appear to have been overestimated.

5.2 The PBAC noted that the submission did not present estimates of use, and that the estimated additional PBS/RPBS expenditure associated with the revised RSA versus the existing RSA was estimated by the Department to be $[redacted] million over 4 years. The PBAC considered that there should not be a cost to Government associated with establishing a new RSA or lapsing of the current subsidisation caps.

5.3 The PBAC recalled that in its November 2016 recommendation for listing for IPF, the Committee recommended an RSA to cap Government financial expenditure based on the submission's estimates for treated patients and adjusted for the continuation rule. The Committee recommended that a [redacted]% rebate should apply to any Government

expenditure beyond the financial cap (paragraph 6.49, nintedanib public summary document [PSD], November 2016 PBAC meeting). The Committee considered a number of factors in recommending an RSA, including:

- that a remaining area of uncertainty was the rate of uptake of nintedanib. The PBAC considered that uncertainty in costs arising from the submission and DUSC estimates of uptake should be addressed through the recommended RSA (paragraph 7.11, nintedanib PSD, November 2016 PBAC meeting).
- the nintedanib model may have resulted in an underestimate of incremental benefit and thus an overestimate of the ICER per QALY. The PBAC concluded that the cost effectiveness of nintedanib would be acceptable in conjunction with risk sharing measures to provide additional certainty (paragraph 7.10, nintedanib PSD, November 2016 PBAC meeting)
- that the risk of continued treatment in patients whose condition has deteriorated (and may no longer be cost effective) should be managed through the RSA (paragraph 6.48, nintedanib PSD, November 2016 PBAC meeting).

The PBAC maintained that the RSA in its current form was addressing these uncertainties.

5.4 The PBAC also recalled that in its recommendation for PF-ILD in September 2021, while the sponsor's financial estimates and RSA had not accounted for potential overlap between ILD and PF-ILD, the PBAC had considered the RSA proposed by the sponsor would be adequate to mitigate the risk of expenditure associated with use outside the eligible population. The PBAC noted that based on actual expenditure data to date, the original estimates for PF-ILD appear to have been significantly overestimated. The PBAC considered that combining the PF-ILD and IPF RSAs as proposed would effectively overestimate the caps compared to actual utilisation, and thus decrease the robustness of the IPF RSA.

5.5 The PBAC noted that this submission was not eligible for an Independent Review.

Outcome:
Not recommended

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

7 Sponsor's Comment

The sponsor had no comment.