\$92.35



November 6, 2024

Lantheus (LNTH): Pylarify Post-Earnings, Still Expecting Cut

We continue to believe that CMS is likely to issue a revised hospital outpatient payment rate for **Lantheus' (LNTH)** Pylarify in the coming days / weeks that would reduce the Medicare per service rate by ~45% (from \$5,753 to \$3,109) relative to both current (4Q24) payments and what was released as part of the CY25 payment rule on Friday. In short, we did not hear anything in the company's 3Q24 earnings call this morning to change our initial <u>takeaways</u> published earlier this week.

CMS DATA	PER UNIT PER SERVICE		%∆
Avg Units Per Service		9.35	
4Q24 Payment	\$615.116	\$5,752.89	
CY25 Addendum B	\$615.116	\$5,752.89	0%
CY25 Mean Unit Cost	\$332.440	\$3,109.15	-46%

Source: CMS, Capitol Policy Partners

By way of reminder, Pylarify (HCPCS A9595) <u>currently</u> receives \$615.116 per unit under its transitional pass-through (TPT) payment, which is due to expire at YE24.

Note: So that investors do not merely need to take our word for it, we have elected to use screenshots from relevant CMS files where possible.

HCPCS Code	Short Descriptor	SI	APC	Relative Weight	Payment Rate
A9595	Piflu f-18, dia 1 millicurie	G	9430		\$615.116

Source: CMS

With the <u>Cost Statistics File</u> published as part of the CY25 final rule showing an average of 9.35 units used per Pylarify service – based on CY23 claims data – this equates to an average payment rate of \$5,753 per service. However, that file also shows a **Mean Unit Cost (MUC)** of \$332.44, which would translate into hospital *costs* per service of \$3,109. This is 46% *below* the 4Q24 payment rate, leaving facility margins of \$2,644 (85%) per service.

2023 HCPCS	2023 Short Description	2023 Days	2023 Units	2023 Units Per Service	2023 Total Cost	2023 Minimum Unit Cost	2023 Maximum Unit Cost	2023 Arithmetic Mean Unit Cost
A9595	Piflu f-18, dia 1 millicurie	34,432	322,026	9.35	\$107,055,851	\$0.90	\$5,100	\$332.44

Source: CMS

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52-Week Low:

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Lantheus Holdings Inc (LNTH)				
Price:	\$89.65			
52-Week High:	\$126.89			
52-Week Low:	\$50.20			
Telix Pharmaceuti	cals Ltd (TLX)			
Price:	A\$22.86			
52-Week High:	A\$22.45			
52-Week Low:	A\$8.94			
Novartis AG ADR (N	IVS)			
Price:	\$106.68			
52-Week High:	\$120.92			



Recall, however, that Pylarify's TPT is set to expire YE24, as <u>confirmed</u> by CMS, and the agency has elected to pay for such post-pass-through products based on their MUC "without exception," as noted on <u>page 136</u> of the final rule [our emphasis]:

"We do agree that there could be some value in the use of ASP for determining a payment amount **in the future**; however, if we were to use the ASP methodology, we believe there must be more consistent, validated, and universal reporting in order for ASP to be a viable payment methodology. To maintain a consistent methodology for CY 2025, **we believe it is appropriate to treat all non-pass-through diagnostic radiopharmaceuticals with claims data the same and pay using MUC without exception, such as for products with recent pass-through expiration.**"

Nevertheless, in CMS's *payment* file – known as <u>Addendum B</u> and referenced by LNTH this morning – the agency continues to list a rate of \$615.116 per unit, which is *exactly* identical to the *current* TPT-based payment, while also being \$2,644 *higher* than the published MUC on a per service basis.

HCPCS Code	Short Descriptor	CI	SI	APC	Relative Weight	Payment Rate
A9595	Piflu f-18, dia 1 millicurie	CH	K	9430		\$615.116

Source: CMS

Realistically, whether the payment is based on ASP, MUC, or something else, we view it as improbable that rates would remain *identical* YoY – down to the thousandth of a dollar – amid changes in underlying claims data, the loss of TPT, and CMS's change to a MUC-based payment system. Our combing of the final rule also finds no mention of specific exceptions that would apply to either Pylarify or any other diagnostic radiopharmaceutical product. This observation is made all the more relevant given the "net price compression" acknowledged by LNTH this morning.

Highlighting this point is the fact that the reported MUC in CMS's data files has fluctuated modestly between even this summer's proposal and Friday's release, based only on several additional months of hospital-reported claims data. That figure had also seen slight changes from last year's rulemaking cycle, as one would expect given the agency's practice of updating the claims data it uses for ratesetting as it becomes available.

PYLARIFY DATA	CY24-P (CY22 DATA)	CY24-F (CY22 DATA)	CY25-P (CY23 DATA)	CY25-F (CY23 DATA)
Units Per Service	9.62	9.48	9.34	9.35
Services	21,951	24,535	31,284	34,432
Units	211,242	232,685	292,224	322,026
Mean Unit Cost (MUC	\$339.95	\$339.95	\$337.46	\$332.44
Cost Stats Rate Per Unit	\$580.35	\$580.35	\$337.46	\$580.30
Addendum B Rate Per Unit	\$580.35	\$580.35	\$337.46	\$615.12
RATE PER SERVICE	\$5,585	\$5,504	\$3,152	\$5,753
Source: CMS, Capitol Policy Par	tners			

We therefore view it as extremely unlikely that the hospital-reported MUC would have leapt ~85% between July and now, and in such a way that it perfectly replicates Pylarify's existing payment rate. A far more likely explanation, in our view, is that the figures published in Addendum B of the CY25 final rule inadvertently reflect *current* payment rates, and not those the agency intends to pay in CY25.

While naturally risky to assume errors on the part of CMS rather than some misunderstood policy dynamic, our best explanation for the alternative hypothesis would be that, despite the agency stipulating that it would pay for these products based on MUC "without exception...for products with recent pass-through expiration," that they *did* in fact make an

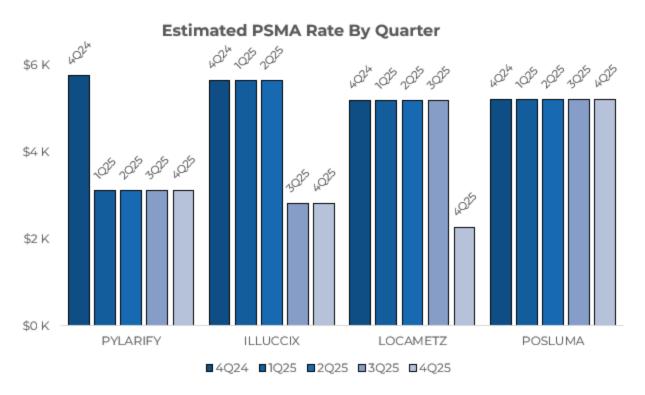


exception – for both Pylarify and several other products – but chose not to acknowledge it. Given that this would likely run afoul of Administrative Procedure Act (APA) disclosure / notification requirements, however, a simple publication error strikes us as more probable, and we would expect to see the agency issue updated payment files in the coming days.

From a competitiveness standpoint, a reduction in Pylarify payments down to the published MUC level would imply facility margins falling to effectively \$0 – given that they would be paid *at cost* – whereas the current delta between payments and MUC would continue for the likes of TLX.AU, NVS, and Bracco / Blue Earth (private) until their own pass-through payments expire on July 1, 2025, Oct. 1, 2025, and Oct. 1, 2026, respectively.

PAYMENT RATE VERSUS MEAN UNIT COST	LANTHEUS PYLARIFY	TELIX ILLUCCIX	NOVARTIS LOCAMETZ	BRACCO POSLUMA
Product Payment	\$5,753	\$5,640	\$5,195	\$5,213
Product Cost	\$3,109	\$2,812	\$2,266	\$2,829
Delta (\$)	\$2,644	\$2,828	\$2,929	\$2,384
Delta (%)	85 %	101%	129 %	84%

Source: CMS, Capitol Policy Partners



Source: CMS, Capitol Policy Partners



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