\$106.45

\$120.92

\$92.35



November 10, 2024

# Lantheus (LNTH): CMS Corrects Payments, Pylarify Rates Down 46%

**Key Takeaways:** Consistent with our pre- and post-rule expectations [here, here, here], CMS this weekend has updated the payment tables released with its CY25 hospital outpatient rule on Nov. 1, reducing the per unit rate for **LNTH**'s Pylarify by 46% from the originally published \$615 to the hospital-reported Mean Unit Cost (MUC) of \$332. With an average of 9.35 units per service, this yields a reduction in hospital payments from \$5,753 to \$3,109, bringing implied facility margins down from 85% to 0%. Also as expected, payments / margins for competitor imaging agents remain constant, and will likely remain so until each of their respective transitional pass-through (TPT) payments expires [TLX.AU (July 1, 2025), NVS (Oct. 1, 2025), privately-held Bracco (Oct. 1, 2026)].

MEASURE	LANTHEUS PYLARIFY	TELIX ILLUCCIX	NOVARTIS PYLARIFY	BRACCO POSLUMA					
UNITS PER SERVICE	9.35	5.50	5.95	8.00					
NOV. 1 RELEASE									
Payment Per Unit	\$615	\$1,026	\$873	\$652					
Mean Unit Cost (MUC)	\$332	\$512	\$381	\$354					
Payment Per Service	\$5,753	\$5,640	\$5,195	\$5,213					
Mean Cost Per Service	\$3,109	\$2,812	\$2,266	\$2,829					
Margin (\$)	\$2,644	\$2,828	\$2,929	\$2,384					
Margin (%)	85%	101%	129%	84%					
UPDATED FILES									
Payment Per Unit	\$332	\$1,026	\$873	\$652					
Mean Unit Cost (MUC)	\$332	\$512	\$381	\$354					
Payment Per Service	\$3,109	\$5,640	\$5,195	\$5,213					
Mean Cost Per Service	\$3,109	\$2,812	\$2,266	\$2,829					
Margin (\$)	\$0	\$2,828	\$2,929	\$2,384					
Margin (%)	0%	101%	129%	84%					
Delta (\$)	(\$2,644)	\$0	\$0	\$0					
Delta (%)	-46%	0%	0%	0%					

Source: CMS, Capitol Policy Partners

Investors will recall that, upon finalizing its CY25 policy of providing separate payments for diagnostic radiopharmaceuticals without TPT, CMS set the *basis* for such payments at MUC, <u>writing</u> that it will "pay using MUC, **without exception**, such as for products with recent pass-through expiration" [*our emphasis*]. With Pylarify's pass-through set to expire at YE24, this policy would appear to apply to them as well, implying a significant drawdown from the current TPT payment of \$615 per unit / \$5,753 per service.

## John Leppard

202-935-0238

Price:

52-Week High:

52-Week Low:

john.leppard@capitolpolicypartners.com

Price:	\$87.50
52-Week High:	\$126.89
52-Week Low:	\$50.20
Telix Pharmaceution	cals Ltd (TLX)
Telix Pharmaceution	cals Ltd (TLX) A\$22.99
	` '



Despite the <u>Cost Statistics File</u> published with the rule release on Nov. 1 showing an MUC of \$332, the actual *payment* file – known as <u>Addendum B</u> – had continued to show a per unit rate of \$615, identical to the soon-to-expire TPT. We had therefore voiced our belief that "the rates included in CMS's Addendum B payment tables were published in error, as has been the case in previous rulemakings, and would expect to see these updated (without fanfare) in the coming weeks."

It is therefore unsurprising that the CY25 final rule's addenda files now show an update having been made on Nov. 7 at 5:12 pm, with the figures modified to be consistent with MUC and the text of the rulemaking itself, rather than the expiring TPT provisions.

Name	Туре	Compress	Password	Size	Ratio	Date modified
2025 NFRM Addendum A.11072024	Microsoft Excel W	86 KB	No	90 KB	4%	11/7/2024 5:12 PM
2025 NFRM Addendum B.11072024	Microsoft Excel W	865 KB	No	895 KB	4%	11/7/2024 5:12 PM
2025 NFRM Addendum C.11072024	Microsoft Excel W	401 KB	No	498 KB	20%	11/8/2024 9:12 AM
2025 NFRM Addendum D1.10242024	Microsoft Excel W	13 KB	No	16 KB	20%	11/1/2024 11:30 AM
2025 NFRM Addendum D2.10102024	Microsoft Excel W	8 KB	No	11 KB	28%	11/1/2024 11:32 AM
2025 NFRM Addendum E.10102024	Microsoft Excel W	60 KB	No	69 KB	14%	11/1/2024 11:32 AM
2025 NFRM Addendum J.10282024	Microsoft Excel W	2,542 KB	No	2,850 KB	11%	11/1/2024 11:34 AM
2025 NFRM Addendum L.10212024	Microsoft Excel W	28 KB	No	30 KB	9%	10/30/2024 5:28 PM
2025 NFRM Addendum M.10102024	Microsoft Excel W	15 KB	No	18 KB	16%	11/1/2024 11:41 AM
2025 NFRM Addendum N.103029924	Microsoft Excel W	16 KB	No	19 KB	16%	10/30/2024 3:01 PM
2025 NFRM Addendum 0.11012024	Microsoft Excel W	25 KB	No	30 KB	17%	11/1/2024 10:55 AM
2025 NFRM Addendum P.11072024	Microsoft Excel W	329 KB	No	334 KB	2%	11/8/2024 9:13 AM
2025 NFRM Addendum Q.11072024 Source: CMS CY25 NFRM OPPS Addenda	Microsoft Excel W	27 KB	No	32 KB	15%	11/7/2024 5:48 PM

Investors will recall that product pass-through payments are based on *manufacturer* reported Wholesale Acquisition Cost (WAC) or Average Sales Price (ASP), whereas MUC is based on cost data provided by *hospitals*. It is the discrepancy between these two figures that led CMS to rely on the latter rather than the former in establishing its diagnostic radiopharmaceutical payment policy, particularly with ASP representing the more traditional approach to drug reimbursement:

"There are very few manufacturers reporting ASP for their products currently, and of those few manufacturers reporting ASP, the ASP values that we do have generally do not align with the ASP we would expect based on the cost data submitted to CMS by hospitals... 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 for ASP to be a viable payment methodology."

With that in mind, we suspect that CMS *eventually* intends to pursue an ASP-based methodology, which would potentially increase payments for Pylarify and other such products in the *future*. However, with MUC-based reimbursement established <u>annually</u>, this is unlikely to take place before CY26 or – more likely, in our view – CY27, given the need for the agency to first develop, formally propose, solicit feedback, and finalize the methodology to be used by *all* manufacturers of diagnostic radiopharmaceuticals.



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