CMS Final IPAY 2028 Guidance for the IRA Medicare Part B Price Negotiations

Halozyme Position Statement

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Forward Looking Statements

In addition to historical information, the statements set forth in this presentation include forward-looking statements including, without limitation, statements concerning the Company's expected future financial performance, including the Company's expectations of the impact to future royalty revenue as a result of implementation of IPAY price negotiations for Part B drugs, the portion of future projected ENHANZE® global sales derived from U.S. Medicare Part B ales through 2028 and the assumptions used in deriving these projections, and factors such as orphan drug status and the potential launch of biosimilars resulting in exclusion from Medicare price negotiation. Forward-looking statements regarding the Company's ENHANZE® drug delivery technology include the possible benefits and attributes of ENHANZE® including its potential application to aid in the dispersion and absorption of other injected therapeutic drugs and facilitating more rapid delivery and administration of higher volumes of injectable medications through subcutaneous delivery and potential to decrease treatment burden and provide clinically meaningful benefits to patients, and lowering healthcare system and Medicare costs including enabling administration at lower cost sites of care. These forward-looking statements are typically, but not always, identified through use of the words "expect," "believe," "enable," "may," "will," "could," "can," "durable," "growth," "innovate," "develop," "vision," "potential," "intends," "estimate," "anticipate," "plan," "predict," "probable," "potential," "possible," "should," "continue," and other words of similar meaning and involve risk and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. Actual results could differ materially from the expectations contained in these forward-looking statements as a result of several factors, including unexpected levels of revenues received from Medicare Part B sales, unexpected changes in the exclusions to Medicare price negotiations or delays in the launch of biosimilars referred to in this presentation, unexpected adverse events or patient outcomes, competitive conditions and uncertainties related to future pharmaceutical pricing policies. These and other factors that may result in differences are discussed in greater detail in the Company's most recent Annual Report on Form 10-K and Forms 10-Q filed with the Securities and Exchange Commission, including under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations". The Company undertakes no obligation to update or revise any forward-looking statements or any other information contained herein.

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Summary

- CMS final comments communicate no impact to IPAY Part B policy for fixed combination products until 2029 at earliest, if CMS were to finalize such a policy
- Strong clinical and pharmacoeconomic evidence of benefit of SC administration of ENHANZE® partner products demonstrated
- Halozyme's interpretation of IPAY Part B policy reinforces zero to minimal impact to future partner royalties
- Halozyme projects royalty revenue impact is zero in 2028, zero to minimal impact 2029-2031and zero to minimal impact to at least 2035

CMS Final IPAY 2028 Guidance for the IRA Medicare Part B Price Negotiations
CMS Response to Comments Related to Fixed Combination Drugs; pages 15-16

Response: CMS thanks the commenters for their feedback on how the existing fixed combination drug policy could impact negotiation eligibility and selection of drugs payable under Part B and how CMS might consider grouping some such fixed combination drug products with products containing at least one but not all of the active moiety(ies) / active ingredient(s) into the same potential qualifying single source drug for both drugs payable under Part B and/or covered under Part D. CMS agrees with the concerns cited by commenters that manufacturers may use CMS' existing fixed combination drug policy to avoid aggregation and therefore selection for negotiation by making minor changes to an existing drug. Due to the complexity and scope of this issue as noted above in stakeholder comments, CMS believes additional time would be necessary to develop objective policy criteria if CMS were to finalize such a policy, and thus will not make a change to the fixed combination drug policy in this final guidance. CMS intends to address this program integrity risk and is continuing to consider the appropriate policy to implement in rulemaking beginning in initial price applicability year 2029. For initial price applicability year 2028, CMS will maintain its approach to fixed combination drugs which states that if a drug is a fixed combination drug[13] with two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying potential qualifying single source drugs. A product containing only one (but not all) of the active moieties / active ingredients that is offered by the same NDA / BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate potential qualifying single source drug. Section 30.1 of this final guidance details how CMS intends to treat fixed combination drugs and gives an example to illustrate the application.

[13] For purposes of the Negotiation Program, the term "fixed combination drug" has the meaning specified in 21 C.F.R. § 300.50.

https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf

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Highlight added by Halozyme

Halozyme Clinical & Pharmacoeconomic Research Demonstrated that SC Delivery, Including With ENHANZE®, Resulted in Savings to Medicare and Clinically Meaningful Benefits

Medicare Savings

- Halozyme published peer reviewed study in Journal of Medical Economics (2025) that SC delivery of 5 of 7 biologic drugs resulted in meaningful savings to Medicare compared with IV delivery of same drugs (slide 7)

- Halozyme demonstrated in same publication that the annualized savings for DARZALEX FASPRO® was ~$29,000 per patient per year (slide 7)

Clinically Meaningful Benefits

- Halozyme described multiple clinically meaningful benefits demonstrated with SC delivery with ENHANZE® of antibody treatments in its letter to CMS (slide 8 and full letter published on Halozyme website Halozyme-Letter-to-CMS.pdf)

- Halozyme published peer reviewed study in Oncology and Therapy Journal (2025) showed results of what it believes is the first U.S. real world survey of patients with cancer experienced with both SC and IV-delivered care
  - 89.6% of patients indicated a preference towards SC delivery versus 5.5% towards IV
  - 78.6% of patients were more satisfied-to-very satisfied with SC delivery versus 33.3% IV, often owing to a reduced treatment burden and improved independence, convenience, and ability to cope with their illness (slide 9)

Halozyme is committed to continue clinical and pharmacoeconomic research to demonstrate the value of ENHANZE® SC administered products

SC Delivery of 5 of 7 Biologic Drugs Resulted in Meaningful Cost Savings to Medicare Compared with IV Delivery of Same Drugs

Table 3. Comparison of mean total spend[a] post-index.

Index drug	IV patients PPPM total spend	SC patients PPPM total spend	IV difference to SC PPPM	Annualized difference (IV to SC)	*P*-value	Difference ratio
Abatacept	$10,395	$9,183	$1,212	$14,539	<0.0001	1.13
Belimumab	$12,341	$9,707	$2,634	$31,612	<0.0001	1.27
Daratumumab	$68,816	$66,387	$2,429	$29,147	<0.0001	1.04
Infliximab	$8,381	$8,428	−$47	−$566	0.6507	0.99
Tocilizumab	$13,243	$8,573	$4,669	$56,031	<0.0001	1.54
Trastuzumab/ Pertuzumab	$32,425	$32,485	−$2	$19	0.9987	1.00
Vedolizumab	$12,895	$11,684	$1,211	$12,536	<0.0001	1.10

Abbreviations: IPTW: Inverse Probability Treatment Weighting; IV: intravenous; PPPM: per study patient per month; SC: subcutaneous.
Results are presented as PPPM due to the varying length of observations for some patients in the post-index period. Total spend includes mean PPPM and were calculated using a gamma regression model with IPTW weighting (variables per drug provided in Supplemental Table 3). The difference ratio was calculated as IV PPPM divided by SC PPPM. Green shading indicates higher spend for IV delivery. Grey shading indicates no significant difference between routes.
[a]Total spend is the sum of all payers: Medicare, patient out-of-pocket, and any third-party payers (less than 1% of claims on average).

Comparison of utilization and total Medicare fee-for service expenditures for subcutaneous versus intravenous versions of select group of therapies; Peter Kardel, Caitlin Sheetz, Jason Maynard and Philip Sarocco. Journal of Medical Economics 2025, Volume 28, No 1, 1541-1550

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SC Delivery With ENHANZE® Results in Clinically Meaningful Benefits

When compared to an antibody given intravenously as a single component product, subcutaneous delivery of a fixed combination containing Halozyme's human hyaluronidase and the specific antibody can enable, for example:

- Meaningfully lower incidence of infusion-related reactions, a potentially life-threatening side effect;
- Meaningfully lower incidence of serious adverse events (SAEs) that result in hospitalization and death;
- Meaningfully improved overall survival;
- Improved patient comfort and decreased emotional distress associated with treatment;
- A reduction in patient treatment time and patient costs related to the site of treatment care;
- A reduction in infection risk by eliminating the need for an intravenous access device (e.g. a port) in some patients;
- A reduction in cancer patients' exposure to infections by reducing the length of time spent in hospital infusion centers;
- A reduction in HCP resources and time required for treatment preparation and administration; and
- A reduction in the chance of a dosing error by the use of a fixed dose combination that does not require the pharmacist to calculate the dose based on individual patient weight.

Excerpted from Halozyme Comment Letter to CMS dated June 25, 2025
Halozyme-Letter-to-CMS.pdf

SC Delivery Preferred by 89.6% Patients Versus 5.5% for IV

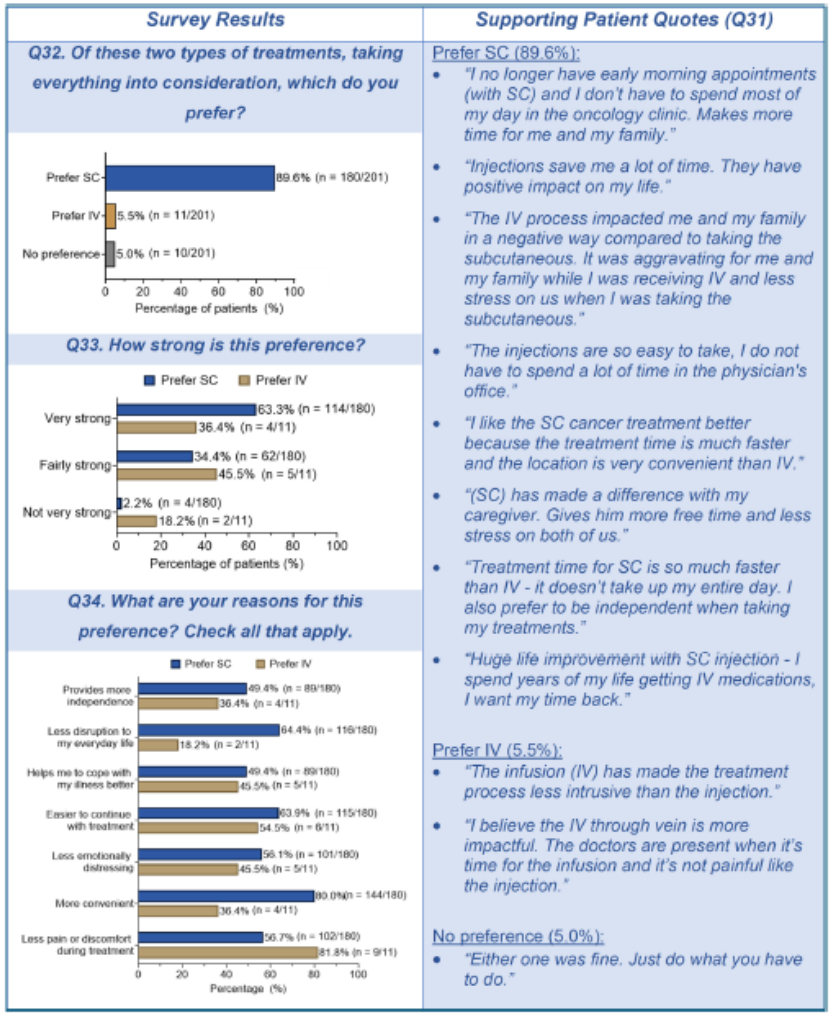

Fig. 1 Patient preferences between SC and IV administration. *IV* intravenous, *Q* question, *SC* subcutaneous

Real-World Quantitative Insights into the Treatment Experience of Patients with Cancer in the USA with Subcutaneous Versus Intravenous Drug Delivery
Robert Epstein · JoAnn Krenitsky · Phillip Sarocco

Oncol Ther. 2025 Sep;13(3):695-710. doi: 10.1007/s40487-025-00360-4. Epub 2025 Jul 16.

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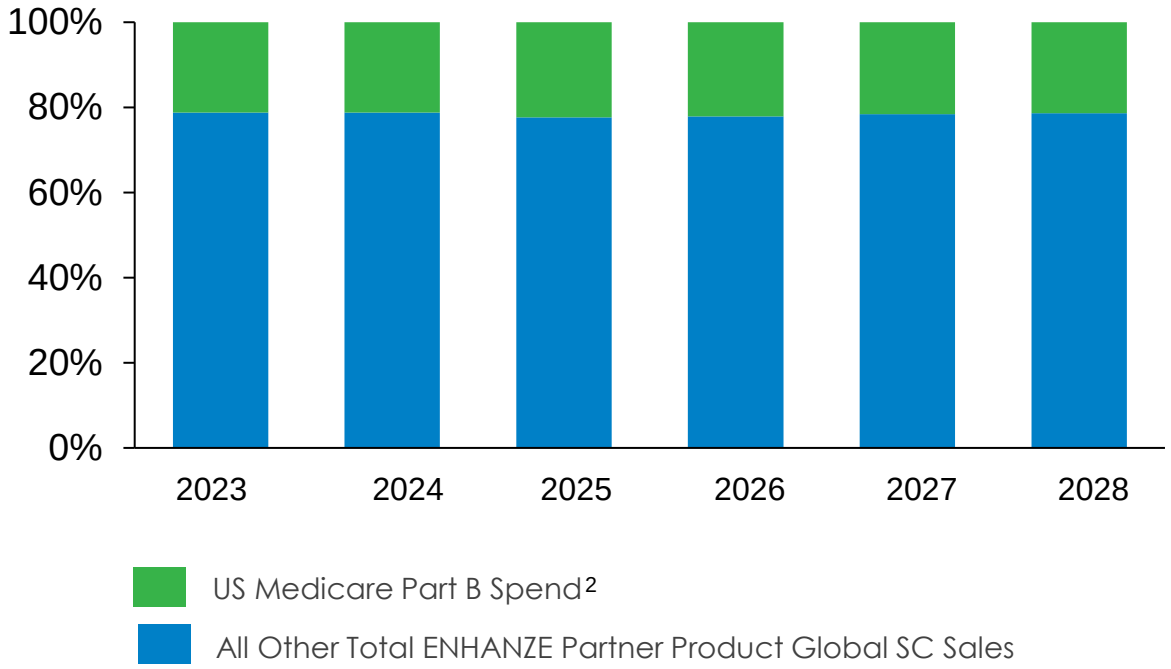
IPAY 2028 Final Guidance
Projected to Result in Zero Part B Price Negotiation Impact in 2028

U.S. Medicare Part B Spend Projected to Represent ~20% of Total ENHANZE® Partner Product SC Sales[1]



Zero projected impact in 2028 due to:

- CMS communicated no changes to IPAY Part B policy for fixed combination products until 2029 at earliest
- DARZALEX FASPRO® excluded from Part B negotiations as all indications have orphan designation[3]
- Opdivo® excluded from Part B negotiations in 2028 as first indication has orphan designation[3]

[1]2023 and 2024 Total ENHANZE® partner product global SC sales based on partner royalty reports, 2025-2028 reflects SC sales projections based on approved ENHANZE® products and assumes global approval and launch of Amivantamab SC. Partner product revenue projections based on Evaluate Ltd analyst-based estimates as of June 2025, when available, otherwise, based on select analyst estimates. Conversion rates based on actual and Halozyme projected SC conversion rates. 2023-2024 Fx conversion based on actual contractual conversion rates, 2025-2028 projections reflect analyst-based estimates in USD from Evaluate Ltd. and select analyst estimates in USD as of June 2025.

[2]U.S. Medicare SC spend is projected based on 2023 Medicare Part B Spending by Drug (https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug/data). The % US Medicare Spend is calculated by dividing US Medicare USD spend by total ENHANZE® partner product global SC USD sales

[3] https://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm

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Halozyme Projects Minimal, to No, Impact to Future Royalty Revenue As a Result of IPAY 2028 Guidance for the IRA Medicare Part B Price Negotiations

Zero Projected Royalty Revenue Impact for 2028

- No impact in 2028 due to no changes to IPAY Part B policy for fixed combination products until 2029 at earliest, if CMS were to finalize such a policy
- Under One Big Beautiful Bill Act ("OBBBA"), drugs with only multiple orphan indication designations are excluded from IRA price negotiations, and for drugs with both orphan and non-orphan designations, the potential impact would occur 13 years after the day after the approval for the non-orphan indication
  - Darzalex all approved indications have orphan designation[1]
  - Opdivo® first indication has orphan designation[1]. Based on the timing of the first non-orphan indication, the potential price negotiation reduction is projected to be delayed to 2029, unless a biosimilar has launched

Zero to Minimal Projected Royalty Revenue Impact for 2029, 2030, 2031

- **Zero to minimal eligibility due to**
  - One Big Beautiful Bill Act ("OBBBA") orphan drug exclusion projected to remain
  - Launch or projected launch of a biosimilar within 2 years of IPAY eligibility expected to result in exclusion from price negotiation[2]; projected to result in exclusion of Opdivo® and Ocrevus®

ENHANZE® products not eligible for Part B price negotiation until 2035+

- Vyvgart® was approved in 2021, earliest impact in 2035 (+13 years) if eligible; both current indications have orphan designation
- Rybrevant® (aminvantamab IV) was approved in 2021, earliest potential impact in 2035 (+13 years)
- Any new current unapproved ENHANZE® SC products would not be impacted for 13 years post launch, if eligible

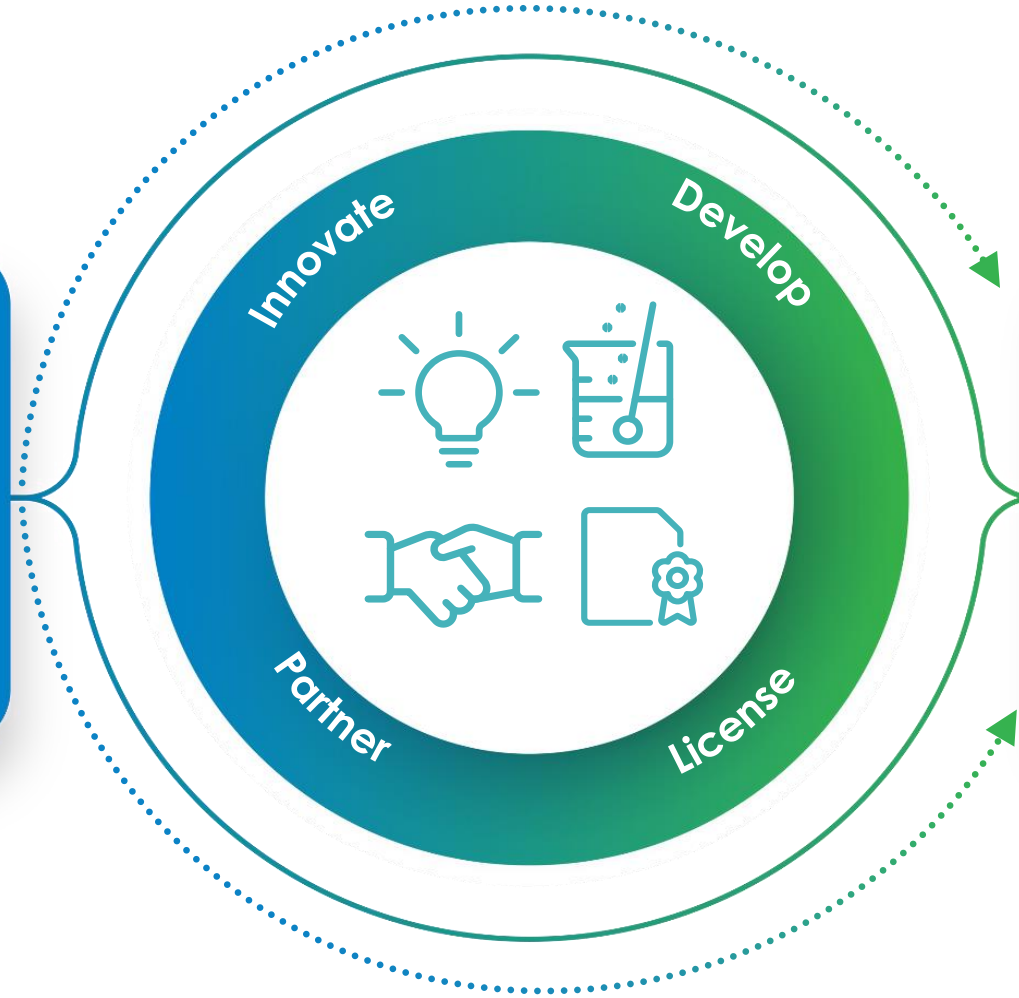
[1] https://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm

[2] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Extends Halozyme's Vision and Broadens Offerings in Drug Delivery

Today

Many breakthrough therapies **require the patient's life to fit the treatment**



Our Vision

Breakthrough therapies will **fit the patient's life**

Halozyme is committed to continue clinical and pharmacoeconomic research to demonstrate the value of ENHANZE® SC administered products