Assessing the budget impact and time savings of introducing nivolumab and hyaluronidase SC to patients receiving nivolumab IV across multiple indications on a US healthcare plan

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Background

- Nivolumab (NIVO) is a programmed death-1 (PD-1) inhibitor[1]
- While NIVO is administered as a 30-minute intravenous (IV) infusion, NIVO in combination with hyaluronidase (NIVO+Hyal) administered subcutaneously (SC) has the potential to reduce the administration burden[1-5]
- In December 2024, the US Food and Drug Administration granted approval for NIVO+Hyal SC, a combination drug product containing NIVO and hyaluronidase
- Approval was granted on the basis of results from the phase 3 randomized, open-label CheckMate 67T trial, which demonstrated noninferior co-primary pharmacokinetic exposure, noninferior efficacy in overall response rate, and a comparable safety profile vs NIVO in advanced or metastatic clear cell RCC[6,7]
- With the introduction of NIVO+Hyal SC in the United States, it is anticipated that payers will assess value evidence for the new route of administration across the indications, to determine the potential budget impact

Methods

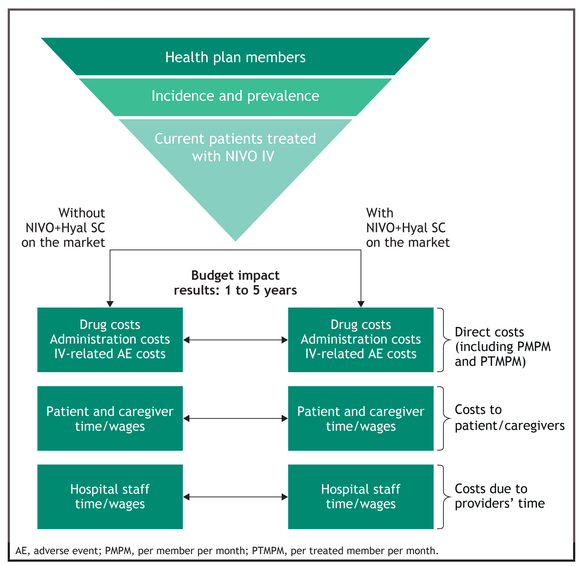
Objective

- To develop a budget impact model that helps inform payers on the anticipated economic and societal impacts of switching from NIVO IV to NIVO+Hyal SC across indications

Model structure

- Budget impact outcomes within a healthcare plan are reported from 3 different perspectives: healthcare payers, patients and caregivers, and providers
- The patient population was determined using incidence and current NIVO IV prevalence by indication
- Budget impacts by indication and overall are estimated as the difference in projected costs between the formulary inclusive of NIVO+Hyal SC and the formulary without NIVO+Hyal SC
- There are 3 options for reporting results (**Figure 1**):
  - Direct costs (including PMPM and PTMPM)
  - Costs to patient/caregivers
  - Costs due to providers' time

Figure 1. Budget impact model schematics



AE, adverse event; PMPM, per member per month; PTMPM, per treated member per month.

- Budget impact was modeled over a 3-year horizon

Model inputs

Incidence of each indication

- Incidence of each tumor location was estimated from the 2020 Surveillance, Epidemiology, and End Results (SEER) Cancer Database
- To determine incidence estimates for each indication subtype (eg, resectable, metastatic, recurring, relapsing), we estimated the proportion of patients meeting the criteria among those who had each tumor location used for SEER-based incidence estimates based on the literature
- NIVO IV market share was obtained from prescription claims data

Market share

- Market share was forecasted for NIVO IV and NIVO+Hyal SC, with NIVO+Hyal SC reaching 50% in year 3
- The IV vs SC market share is assumed to be equal across the 19 distinct NIVO indications included in the model

Adverse events

- The model considers infusion/injection site-related AEs, eg, rash and pruritus, and assumes that the incidence of systemic AEs is likely comparable between NIVO+Hyal SC and NIVO IV
- Grade 3/4 AEs were based on results of the original pivotal trials for NIVO IV, as reported in the NIVO IV prescribing information[1]

Dosing

- Dosing information was based on the NIVO+Hyal SC prescribing information[5]
- NIVO+Hyal SC can be administered every 2 weeks (Q2W), every 3 weeks (Q3W), or every 4 weeks[5]
- The dosing assumption was 100% for Q2W or Q3W where appropriate
- The administration location assumption is 50% within hospital and 50% outpatient

Costs

- For all drugs, the wholesale acquisition cost as of January 2025 was used (NIVO 240 mg IV, $7,787.33; NIVO+Hyal 600 mg SC, $7,787.33)
- Administration cost was based on the Hospital Outpatient Prospective Payment System (OPPS, 2024) and the CMS Physician Fee Schedule[8,9]
- Costs associated with insertion of venous access lines for infusions were included

Treatment duration

- Treatment duration varied by indication and was according to NIVO-specific published literature; however, based on NIVO-specific trial data, the duration was capped at 1 year if treatment duration exceeded 1 year

Patient and caregiver time

- Travel time for patients and caregivers, and chair time at clinics for receiving NIVO, was included

Impact to patients and caregivers

- To estimate indirect costs due to productivity losses for patients and their caregivers, the model multiplied the total hours lost by patients and caregivers by hourly wage

Impact to providers

- The model estimates the impact of introducing NIVO+Hyal SC on time required for drug administrations of NIVO IV and NIVO+Hyal SC
- Healthcare staff time used during pre-administration, treatment administration, and monitoring stages by oncologists, nurses, pharmacists, and technicians was considered in calculating these costs

Results

Aged ≥ 65 years: all indications

- Payers
  - For a healthcare plan with 1 million members aged ≥ 65 years, the introduction of NIVO+Hyal SC (up to 50% switch) resulted in an estimated incremental cost savings of $636,563 over 3 years (**Table 1**)
  - The per member per month (PMPM) budget impact ranged from −1 to −3 cents
  - The per treated member per month (PTMPM) budget impact ranged from −$25 to −$80
- Patients and providers
  - The incremental cost savings were $361,628 over 3 years
  - By year 3, the introduction resulted in time savings of 11,787 patient and caregiver hours and 2,407 hospital staff hours

Table 1. Budget impact of NIVO+Hyal SC vs NIVO IV across modeled indications (for a healthcare plan with 1 million members ≥ 65 years)

All indications	Year 1	Year 2	Year 3
Incremental costs, US$			
Total direct costs	−102,879	−212,188	−321,496
Pharmacy costs	59,675	123,079	186,484
Administration costs	−128,303	−264,625	−400,947
AE costs	0	0	0
Venous access costs	−34,251	−70,642	−107,033
PMPM	−0.01	−0.02	−0.03
PTMPM	−25	−53	−80
Costs to patients/caregivers	−13,799	−28,461	−43,122
Hospital staff costs	−44,646	−92,082	−139,518
Outcomes, hours			
Patient and caregiver time	−3,772	−7,779	−11,787
Hospital staff time	−770	−1,589	−2,407

Aged < 65 years: all indications

- For a healthcare plan with 1 million members aged < 65 years, the introduction of NIVO+Hyal SC (up to 50% switch) resulted in an estimated incremental cost savings of $54,909 over 3 years (**Table 2**)
- The PMPM budget impact was $0
- The PTMPM budget impact ranged from −$36 to −$112
- By year 3, the introduction resulted in time savings of 706 patient and caregiver hours and 144 hospital staff hours

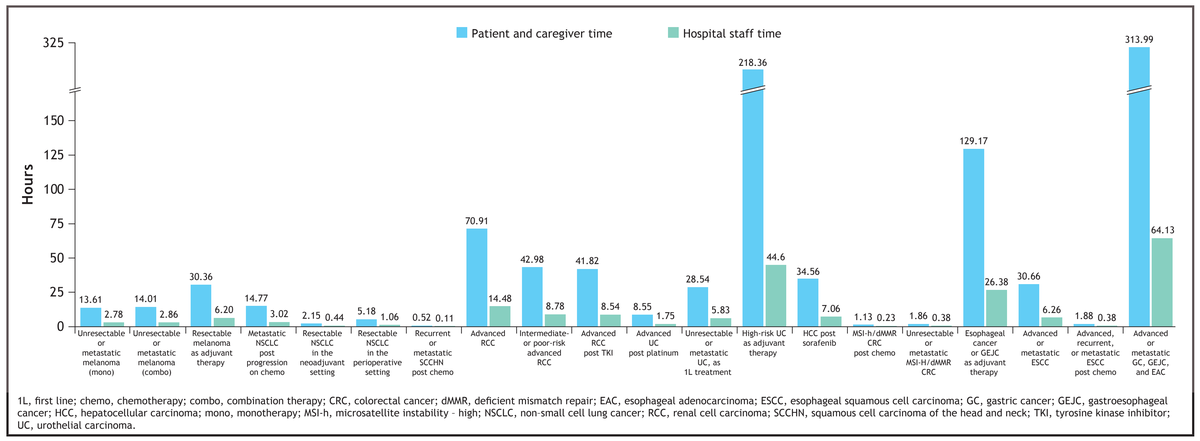
Table 2. Budget impact of NIVO+Hyal SC vs NIVO IV across modeled indications (for a healthcare plan with 1 million members < 65 years years)

All indications	Year 1	Year 2	Year 3
Incremental costs, US$			
Total direct costs	−8,874	−18,303	−27,732
Pharmacy costs	212	438	664
Administration costs	−7,467	−15,400	−23,333
AE costs	0	0	0
Venous access costs	−1,620	−3,341	−5,062
PMPM	0.00	0.00	0.00
PTMPM	−36	−74	−112
Costs to patients/caregivers	−3,280	−6,765	−10,249
Hospital staff costs	−2,674	−5,515	−8,357
Outcomes, hours			
Patient and caregiver time	−226	−466	−706
Hospital staff time	−46	−95	−144

Total time saved for all patients per dose

- **Figure 2** shows the time saved (patient and caregiver time and hospital staff time) per indication for all patients per dose in year 1

Figure 2. Time saved per indication for all patients per dose in year 1 (for all ages, with 1 million plan members)



1L, first line; chemo, chemotherapy; combo, combination therapy; CRC, colorectal cancer; dMMR, deficient mismatch repair; EAC, esophageal adenocarcinoma; ESCC, esophageal squamous cell carcinoma; GC, gastric cancer; GEJC, gastroesophageal cancer; HCC, hepatocellular carcinoma; mono, monotherapy; MSI-h, microsatellite instability – high; NSCLC, non-small cell lung cancer; RCC, renal cell carcinoma; SCCHN, squamous cell carcinoma of the head and neck; TKI, tyrosine kinase inhibitor; UC, urothelial carcinoma.

All ages: individual indications

- **Table 3** shows the total cost savings for year 1 for all ages for each individual indication

Table 3. Difference in total costs for NIVO+Hyal SC vs NIVO IV for each indication (all ages) in year 1

Indications	Change in costs, US$	
	≥ 65 years	< 65 years
High-risk UC as adjuvant therapy	−66,062	−75
Advanced or metastatic GC, GEJC, and EAC	−57,431	−5,139
Unresectable or metastatic UC, as 1L treatment	38,486	36
Esophageal cancer or GEJC as adjuvant therapy	−32,470	−2,126
Advanced RCC	−13,429	−2,562
Advanced RCC post TKI	−8,000	−1,524
Resectable melanoma as adjuvant therapy	−6,314	−916
Advanced or metastatic ESCC	−5,945	−386
Intermediate- or poor-risk advanced RCC	−5,385	−1,102
HCC post sorafenib	−4,572	−391
Metastatic NSCLC post progression on chemo	−4,416	−63
Unresectable or metastatic melanoma (mono)	−2,896	−419
Advanced UC post platinum	−2,659	−3
Unresectable or metastatic melanoma (combo)	−833	−164
Advanced, recurrent, or metastatic ESCC post chemo	−502	−31
Unresectable or metastatic MSI-H/dMMR CRC	−332	−50
MSI-h/dMMR CRC post chemo	−234	−35
Recurrent or metastatic SCCHN post chemo	−112	−19
Resectable NSCLC in the perioperative setting	4,065	47
Resectable NSCLC in the neoadjuvant setting	7,718	93

Conclusions

- NIVO+Hyal SC is projected to generate direct cost savings and neutral budget impact based on PMPM/PTMPM when switching from NIVO IV
- Time savings are expected for patients and hospital staff, which may improve healthcare efficiency and patient experience
- Further real-world studies are needed to validate these modeled findings
- The model does not account for wastage relevant for Q3W dosing schedules, therefore resulting in neutral to slight increased in pharmacy costs

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