

# Identification and Characterization of Real-World Evidence Presented on Brand Websites for the Top 20 Medicines with the Highest CMS Expenditure

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## BACKGROUND

Real-world evidence (RWE) allows for an increased understanding of drug effectiveness, safety, and impact on patients in clinical settings

Pharmaceutical companies communicate RWE through channels such as brand websites to highlight acceptable RWE to appropriate stakeholders

There is an interest to understand the extent to which RWE is being used by pharmaceutical companies to communicate the value beyond clinical trial data on the brand websites

The interest for evidence communication is especially high in the top 20 Centers for Medicare & Medicaid Services (CMS) spending medicines

## OBJECTIVE

To identify and categorize how often and what kind of RWE is being communicated proactively on brand websites for the top 20 CMS spending medicines

## METHODS

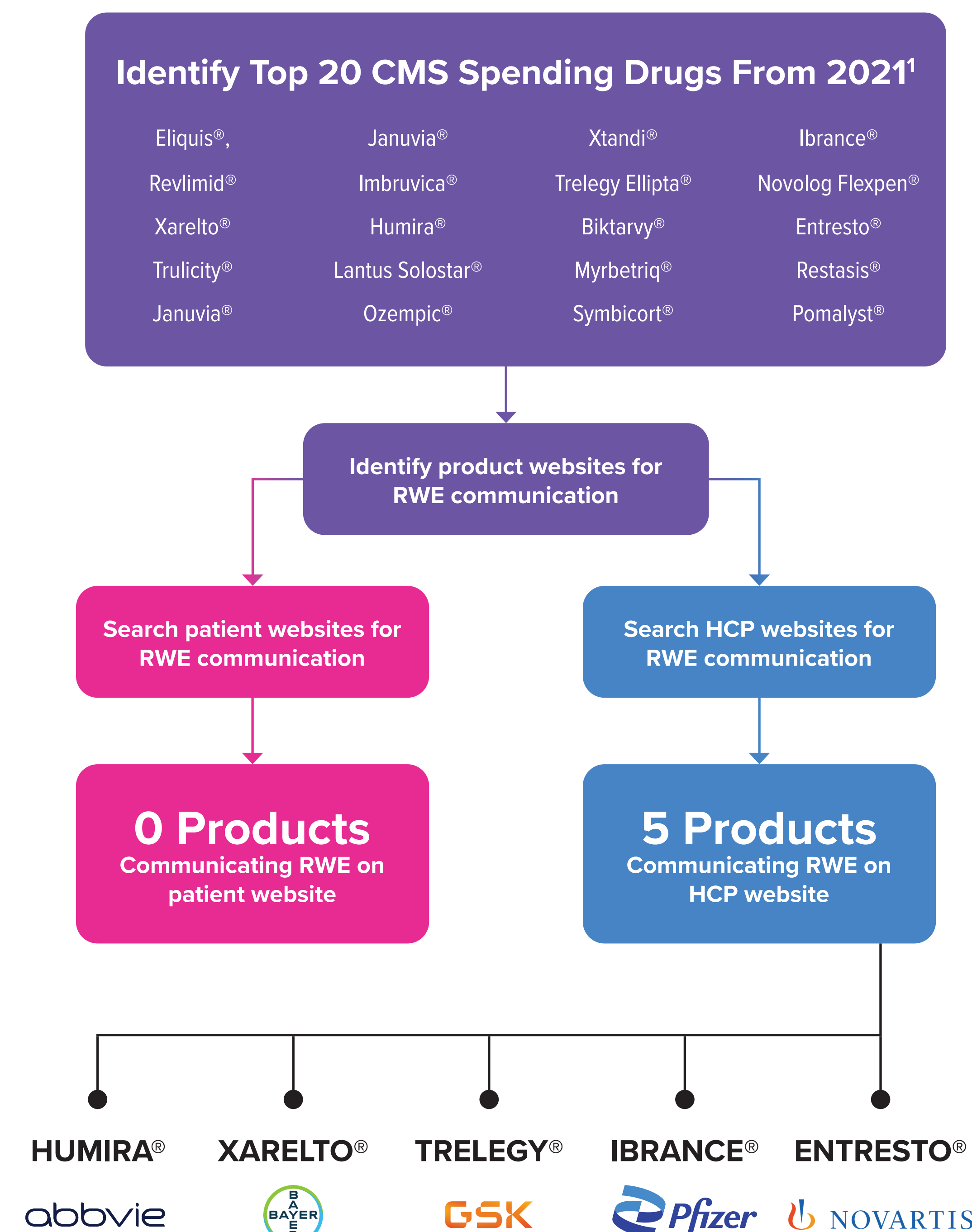
The top 20 CMS spending medicines were identified using CMS.gov<sup>1</sup>

The patient and healthcare professional (HCP) brand websites for each medicine were identified (Figure 1)

Within these websites, keyword searches were conducted to identify whether RWE was communicated on the brand websites

The number of brand websites presenting RWE was quantified and the information was characterized

**Figure 1:** Search strategy to identify the top 20 CMS spending drugs and RWE communicated on brand websites



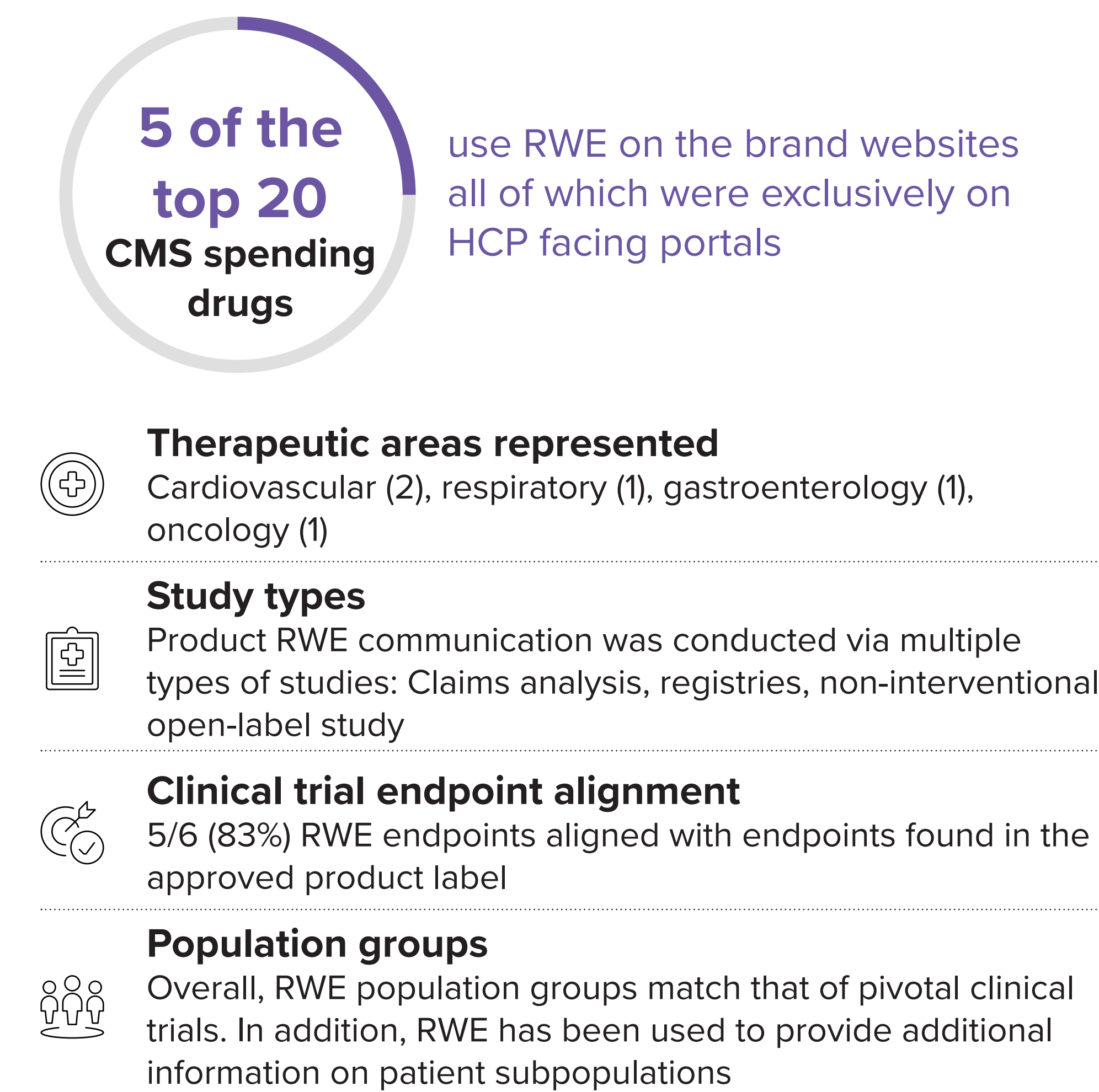
## RESULTS

**Table 1 and Figure 2** summarize the information conveyed on brand websites regarding RWE

**Table 1:** RWE communication on brand websites

Product	Xarelto® (rivaroxaban) Approved Nov-11		Humira® (adalimumab) Approved Feb – 21	Trelegy® (fluticasone/umeclidinium/ vilanterol) Approved Sep – 21	Ibrance® (palbociclib) Approved Feb 2015	Entresto® (sacubitril/valsartan) Approved July 2015
Manufacturer	Bayer		AbbVie	GSK	Pfizer	Novartis
Therapeutic Area	Cardiovascular		Gastroenterology	Respiratory	Oncology	Cardiovascular
RWE Endpoint Referenced on Website	Rates of stroke or systemic embolism in obese patients	DVT incidence	Safety	Reduction in exacerbations in early vs delayed initiation following first COPD exacerbation	Comparative effectiveness	QoL
Publication Type (Date)	Manuscript (2019)	Manuscript (2019)	Abstract (2018) Poster (2018) Data on File	Manuscript (2022)	Manuscript (2022) DOF	Data on File
RWE Study Type	Claims analysis	Non-interventional open label cohort study	Ongoing Registry Study	Claims analysis	Claims analysis	Registry Study
RWE Study Endpoints	Composite risk of ischemic stroke and systemic embolism, bleed risk, HCRU, costs in obese patients	AEs, including bleeding and thromboembolic events, Crude and adjusted incidences were calculated	Registry treatment-emergent: A. AEs B. Serious infections by 2 + patients in either group C. Malignancy	A. Rate of COPD exacerbations B. Time to first overall, moderate, and severe COPD exacerbations C. Median time to exacerbation	A. Real-world PFS B. OS	A. KCCQ-12 (HRQoL Survey)
Active Comparator	Comparator (vs warfarin)	Comparator (vs SOC)	Non-active (single-arm)	Not applicable	Comparator (vs AI monotherapy)	Non-active (single arm)
ClinicalTrials.gov	--	NCT00831714 (Not a PAS study)	NCT01848561 (Not a PAS study)	--	--	--
Study Included in Package Insert	No	No	No	No	No	No
Clinical Trial Endpoint	Rates of stroke or systemic embolism	DVT incidence	Clinical Remission & Safety (serious AEs, infection, malignancy)	Rate of moderate or severe COPD exacerbations	PFS ORR OS	CV death Hospitalizations

**Figure 2:** RWE communication on brand websites



## ABBREVIATIONS

**AE** adverse event  
**CMS** Centers for Medicare & Medicaid and  
**CV** cardiovascular  
**COPD** chronic obstructive pulmonary disease  
**DOF** data on file  
**DVT** deep vein thrombosis  
**HCP** healthcare profession  
**HCRU** healthcare resource use  
**KCCQ** Kansas City Cardiomyopathy Questionnaire  
**PFS** progression-free survival  
**QoL** quality of life  
**RWE** real-world evidence  
**SOC** standard of care  
**PAS** post-approval study

## REFERENCES

1. Centers for Medicare & Medicaid Services (CMS). Medicare Part D Spending by Drug 2021. <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug/data>

## CONCLUSION

RWE is being utilized by manufacturers to highlight product information beyond clinical trial data

RWE is underutilized for the top CMS spending medicines, presenting an opportunity for manufacturers to highlight and leverage RWE on brand websites

## FUTURE DIRECTION/ NEXT STEPS:

Understand the barriers and hesitations to communicating RWE on brand websites by manufacturers

Further expand upon and understand various avenues available for manufacturers to proactively communicate RWE on brand websites

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