

# FAERS Data as Proxy to Determine Total Medical Costs for TNF- $\alpha$ Inhibitors

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## OBJECTIVES

- Examine the downstream medical costs associated with infections linked to the use of TNF alpha inhibitors, which are prescribed for rheumatoid arthritis, psoriatic arthritis, Crohn's disease and ulcerative colitis. The class of drugs includes Humira (adalimumab), Enbrel (etanercept), Cimzia (certolizumab pegol), Remicade (infliximab), Simponi (golimumab), and Simponi Aria (golimumab).
- Determine if Advera Health's Evidex platform validates the hypothesis that FAERS measured ADE incidence for pneumonia would be similar in the WEA Trust medical claims database, with certain TNF alpha inhibitors resulting in a higher incidence of pneumonia and higher downstream medical costs. The study hypothesis was based on data derived from Advera Health's RxScore<sup>®</sup> and RxCost<sup>®</sup> analytics regarding Cimzia's elevated incidence of FDA-reported ADEs.

## BACKGROUND

- ADEs are a more prevalent health threat than currently appreciated in many sectors of the medical community. Better ADE awareness and severity stratification may be achieved by combining signal from the aggregated practitioner reported observations along with other insurance claim data. Combined voluntary reported data and claims data may corroborate a suspected ADE by examining downstream medical costs that are associated with ADEs.
- WEA Trust, a not-for-profit Midwest health insurer serving the public sector, and Advera Health Analytics, Inc., a global health care informatics company specializing in pharmaceutical drug evidence aggregation, including adverse drug event detection, teamed up to use Advera Health's analytics platform, Evidex<sup>™</sup>, which includes post-marketing ADE reporting from the FDA Adverse Events Reporting System (FAERS) in combination with a WEA Trust claims database.

## METHODS

- For the time period of August 1, 2013 through July 31, 2015, WEA Trust built a data extract, including all medical and pharmacy claims, and submitted to Advera Health for analysis. Current Procedural Terminology (CPT) Service Codes were used to establish three areas of downstream cost measurement: emergency room visits, hospitalizations and ambulance transportation. Only medical services incurred after filed pharmacy claims were examined. ICD-9 diagnoses were included in all medical claims and were used to match to listed ADEs for each drug.
- A cost per dispense was calculated to include the downstream medical costs due to emergency room visits over the entire course of the study period.

## CONCLUSIONS

- FAERS data may be a proxy to determine adverse event outcomes in an insured population thereby assisting in lowering costs and improving outcomes through the prevention of adverse events.
- Based on the validation that two TNF inhibitors were shown to be statistically more likely to cause infections and result in higher medical costs, WEA Trust will be working with providers to move members away from these TNF inhibitors in order to provide a safer health benefit at a lower cost.

## CONTACT

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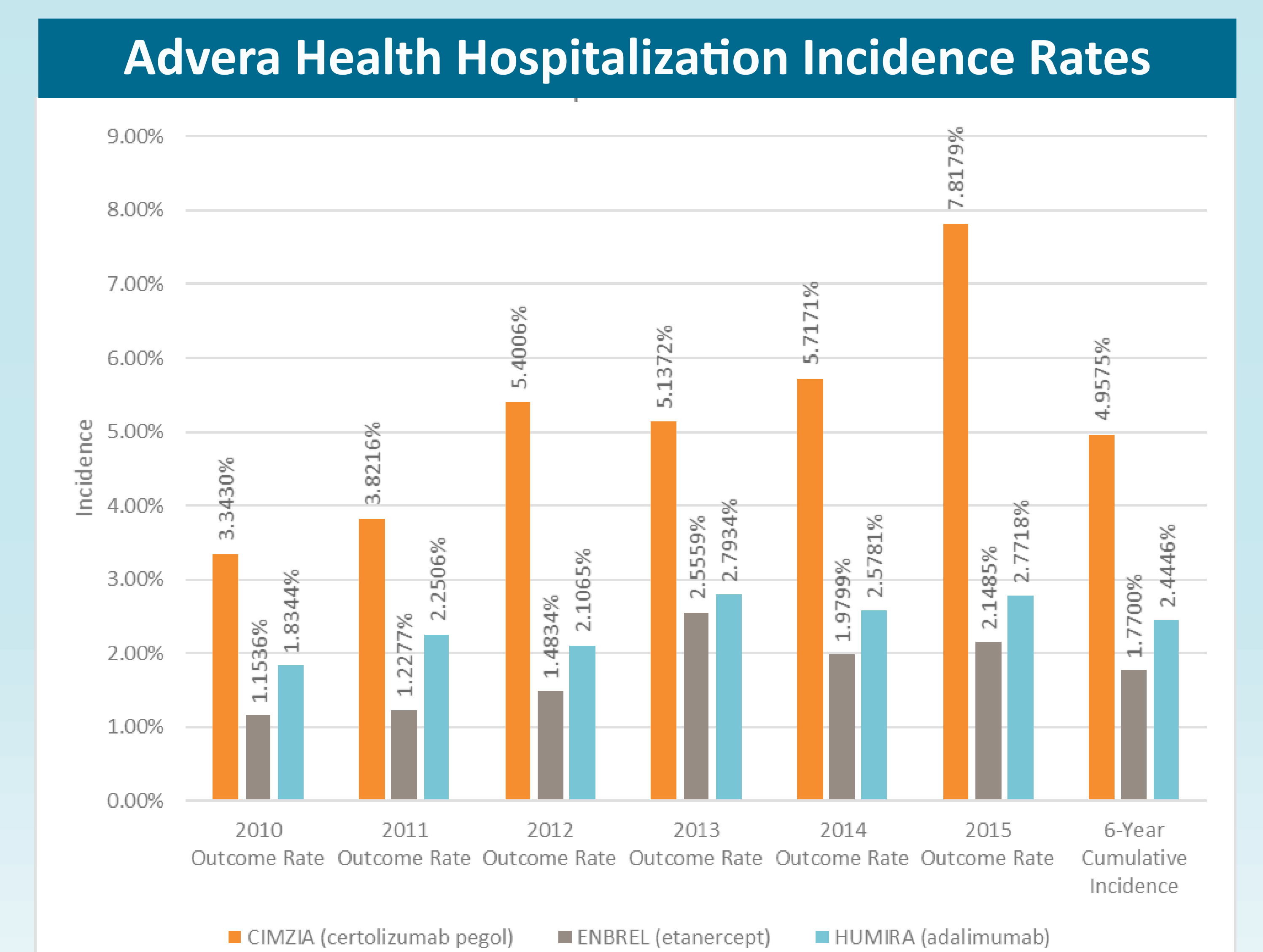
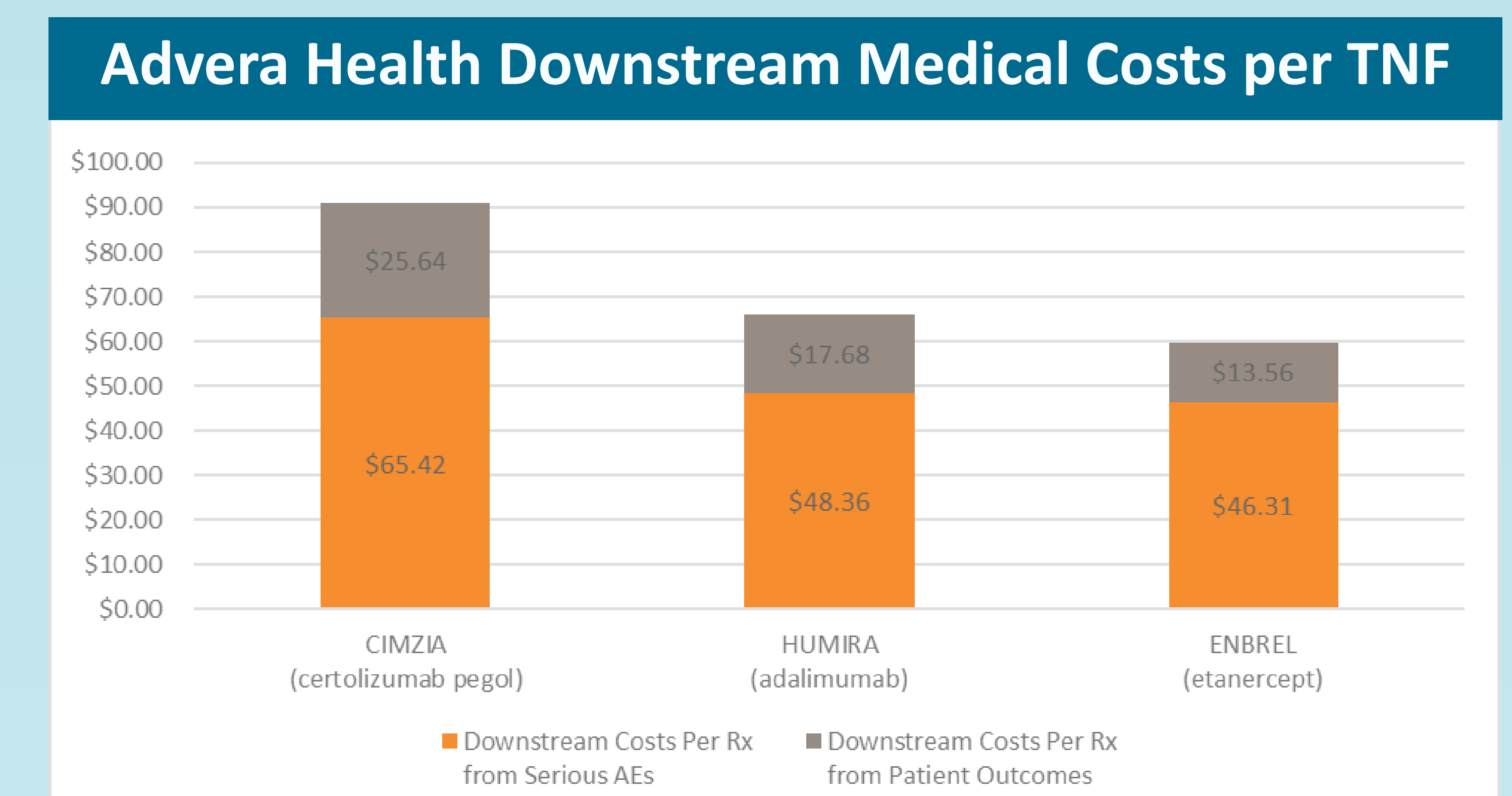
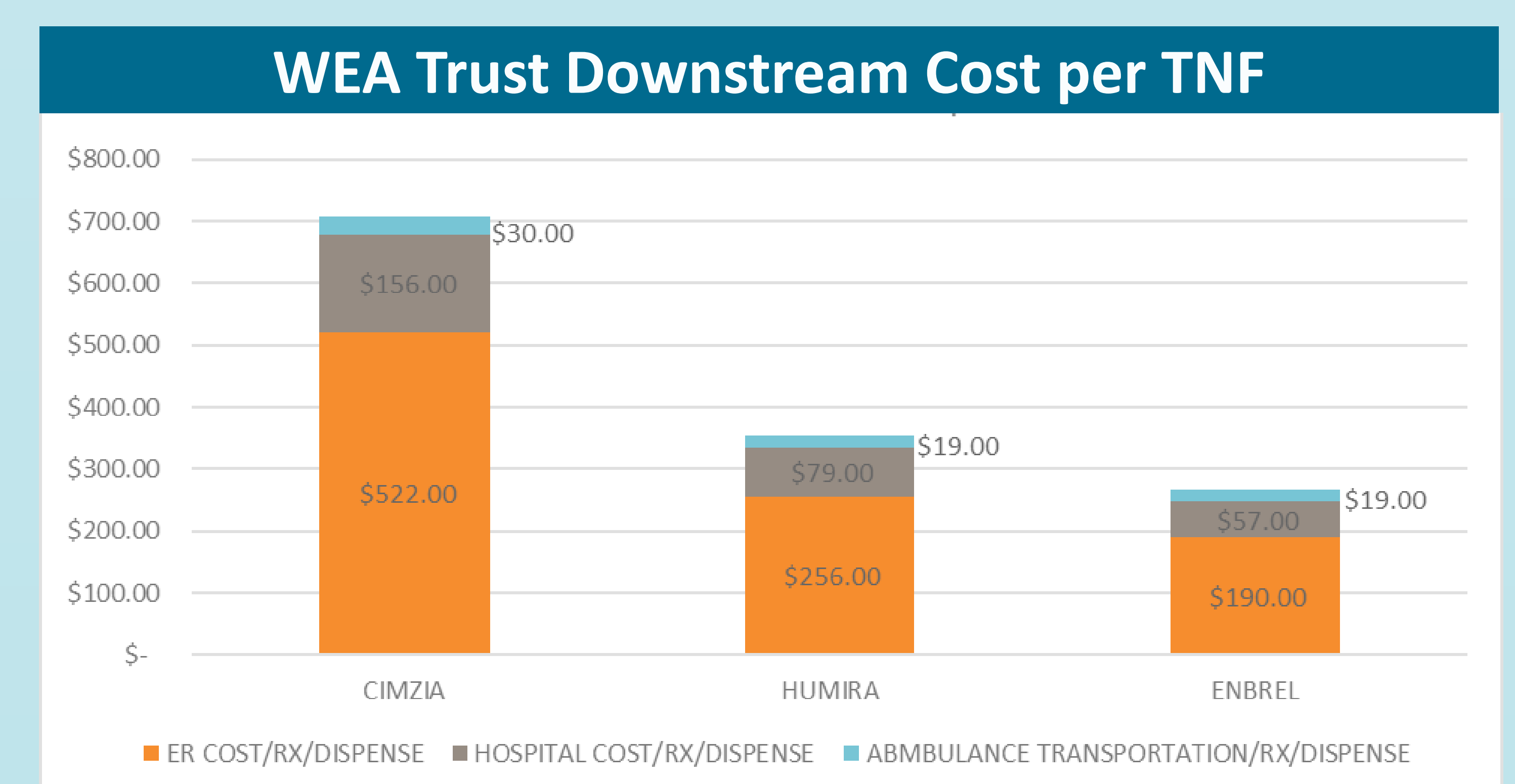
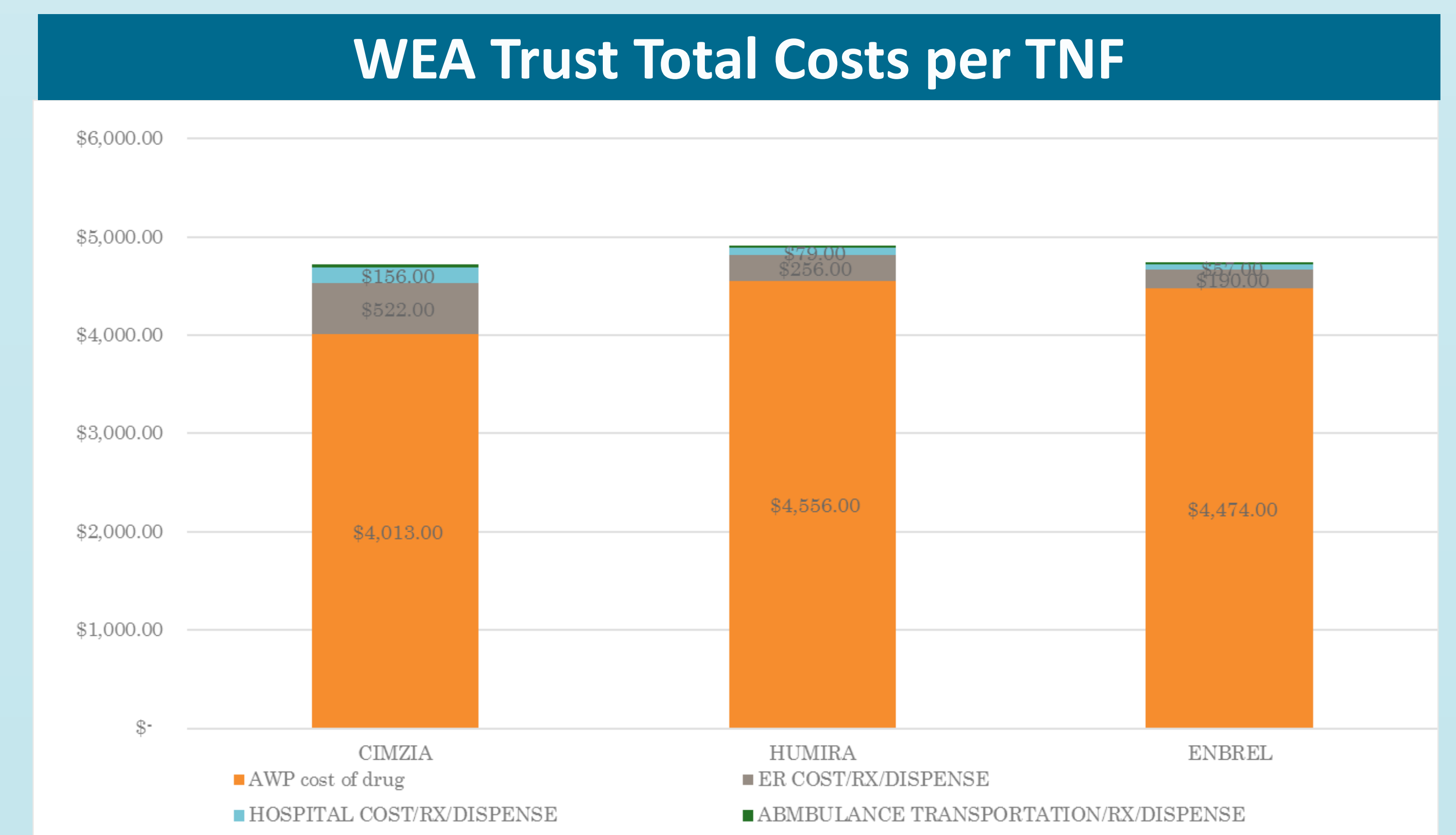
## RESULTS

Cimzia showed to have an incidence rate of 13.6% (n=22) for pneumonia, whereas Simponi an incidence of 40% (n=5), as compared to Humira and Enbrel of 0.5%. The final analysis demonstrated that Cimzia and Simponi were associated with a higher incidence of ADEs as compared to other TNF's (Humira, Enbrel, and Remicade). A cost per dispense was calculated to include the downstream medical costs due to emergency room visits over the entire course of the study period. Cimzia was on average \$522 per dispense as compared to \$256 for Humira and \$190 for Enbrel. The downstream medical costs per dispense due to hospitalizations were \$156, \$79, and \$57 and due to ambulance transportation were \$30, \$19, and \$19 for Cimzia, Humira, and Enbrel, respectively.

**700,000 EMERGENCY DEPARTMENT VISITS AND 120,000 HOSPITALIZATIONS ARE DUE TO ADEs**

Incidence of Pneumonia		
	N=	Pneumonia
Humira	188	0.005 (1) 0.5%
Enbrel	111	0.009 (1) 0.5%
Cimzia	22	0.136 (3) 13.6%
Simponi	5	0.4 (2) 40%

Statistical Significance Tests					
	Significant Difference in Pneumonia Rates	Difference	p-Value	Chi squared	95% CI
Humira vs Enbrel	No	0.4%	0.6777	0.173	-2.303 to 4.4456
Humira vs Cimzia	Yes	13.10%	<0.0001	18.308	2.1293 to 34.3735
Humira vs Simponi	Yes	39.50%	<0.0001	50.395	4.6935 to 84.8394
Enbrel vs Cimzia	Yes	12.70%	0.0015	10.098	1.2610 to 33.9860
Enbrel vs Simponi	Yes	39.10%	<0.0001	28.793	4.1431 to 84.4452
Cimzia vs Simponi	No	26.40%	0.1780	1.814	-14.3208 to 72.9848



## LIMITATIONS

- The duration of treatment of TNF's was not calculated nor compared between classes.
- There was no adjustment made for age or comorbidity.
- There was not analysis of claims to determine if prior exposure to another TNF had occurred.