OBJECTIVES: To assess the trends in average wholesaler prices at market entry for multiple sclerosis (MS) disease-modifying therapies (DMTs) approved by the US Food and Drug Administration (FDA) in the period 1987-2014. METHODS: DMTs’ regulatory information was derived from the FDA website. Average wholesaler prices (AWP) per unit at market entry data were derived from the RedBook (Truven Health Analytics, Inc.). The AWP history was collected from year of approval to October 2014. The daily defined dosage (DDD) for adult patients was obtained from FDA approved labels. AWP per DDD and the AWP per year were computed. Descriptive statistics and Wilcoxon tests were performed. Statistical significance level was set at 0.05. RESULTS: The National Multiple Sclerosis Society listed 11 FDA approved DMTs (5 new drug applications [NDA] and 6 biological license applications [BLA]) as of October 2014. Two products were approved by the FDA using priority review. The FDA granted orphan designation to 5 DMTs. Only one DMT had orphan designation from the FDA in the 1980s, three in the 1990s and 2000s, respectively, and 4 in the period 2010-2014. The median AWP per DDD was $5.88 in the 1990s, $7.13 in the 2000s, $217.52 in the 2000s, and $274.76 in the period 2010-2014. Statistically significant differences were found in median AWP AWP per DDD prices between NDAs and BLAs. The median AWP per DDD was not significantly different for FDA priority review drugs compared to standard review drugs, and for orphan compared to non-orphan drugs. CONCLUSIONS: The median AWP per DDD at market entry increased substantially over time. No statistically significant differences were found in the median AWP per DDD between priority and standard review drugs, and between orphan and non-orphan drugs.

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THE ECONOMIC BURDEN OF SPINAL MUSCULAR ATROPHY
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OBJECTIVES: To evaluate the economic consequences of having spinal muscular atrophy (SMA). METHODS: This study was conducted using Department of Defense Military Health System (MHS) data from 2006 to 2012. Eligible patients had a SMA diagnosis (ICD-9-CM codes 735.0 or 351.5) on 1 inpatient or 3 outpatient claims before 18 years of age. Individuals had at least 6 months of data after first SMA diagnosis; or died within 6 months after first SMA diagnosis; or had at least 12 months of data before first SMA diagnosis. Subgroup analyses were conducted for early (<1 years) and late diagnosis (>1 years). RESULTS: A total of 239 individuals met the inclusion criteria. The median total expenditure, while enrolled in the MHS, was $83,652 (25-75 percentile $29,620-$72,754) over a median observation of 6.9±3.6 years, though rare outlier costs were as high as $4.4 million. The mean age (SD) at first observed SMA diagnosis was 7.5±6.4 years. The mean (SD) duration of observation following initial SMA diagnosis was 4.6±3.3 years with a median cost of $60,213 ($18,229-$192,559). For all patients, the primary cost driver was outpatient costs (median $53,152 $23,902-$136,150), followed by medication costs (median $11,258 ($851,987)) and total prescription costs (median $3,167 [943-$13,283]). The subgroup of patients with early diagnosis (n=45) had 4.3±2.9 years of observation with a median cost of $167,921 ($53,349-$678,412). Approximately 17.8% of this subgroup died during the observation period, which highlights the devastating nature of early onset SMA. Patients with late diagnosis (n=194) had 7.5±4.4 years observation and median total costs of $70,380 ($28,196-$184,272). CONCLUSIONS: Individuals with SMA have a high degree of morbidity and mortality, particularly those diagnosed during infancy. SMA patients have significant medical expenditures and high utilization of health care services. There is significant economic burden caring for patients diagnosed with SMA. DISCLAIMER: Research derived from an IRB approved protocol at Naval Medical Center Portsmouth, VA. The views expressed in this abstract are those of the authors and do not necessarily reflect the official policy or position of the Department of the Army, Department of the Navy, Department of Defense or the United States Government. George J. Dahl and Rees Lee are members of the U.S. military. This work was prepared as part of their official duties. Title 17 U.S.C. 105 provides that “Copyright protection under this title is not available for any work of the United States Government; ‘Title 17 U.S.C. 101 defines a United States Government work.” Work prepared by a military service member or employee of the United States Government as part of that person’s official duties.

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