

2019 SUN LIFE STOP-LOSS RESEARCH REPORT

High-cost claims and injectable drug trends

A photograph of two women in a professional setting, smiling and engaged in conversation. The woman on the left has long dark hair and is wearing a dark patterned top. The woman on the right has braided hair and is wearing a light-colored top. They are sitting at a table with a laptop and some papers. In the background, there are wooden shelves with various items on them.

What's inside

Executive summary	1
Top 10 high-cost claim conditions	2
Cancer: the highest-cost condition	5
Conditions by deductible level	8
Top 20 high-cost injectable drugs	10
Cancer drugs on the rise	14
Million-dollar+ claim trends	16
Stop-loss coverage	20
Recommendations	22
About the study	23



Executive summary

Sun Life has published a research report about current trends in high-cost claim data for the past seven years. These research reports provide a unique perspective on data from the past 10 years based on over 73,000 claimants and over \$6.4 billion in stop-loss reimbursements. This year's report focuses on the latest trends in the top 10 high-cost claim conditions, differences in the top 10 by deductible level, a review of the top 20 high-cost injectable drugs, a detailed look at the highest-cost cancer drugs, and insights on drivers behind the largest claims in 2018. As an organization, we are committed to using our claims data to provide meaningful insights for the self-funded community.

From 2015 to 2018, Sun Life stop-loss claim reimbursements totaled \$3.5 billion. When those reimbursements are added to first dollar claims costs (amount paid by employers before they reach the deductible), the total is over \$7.9 billion for high-cost conditions. This research study included claims data from Sun Life stop-loss policyholders that have approximately 50 to 100,000+ employees across the U.S.

Key findings:

- Cancer continues to top the list as both the #1 and #2 highest-cost claim condition, accounting for 26.8% of the total stop-loss reimbursements. As a result, we are taking a closer look at cancer themes throughout this year's report.
- Breast cancer was the most common type of cancer and also had the highest overall spend, while lymphocytic leukemia was the cancer condition with the highest average cost.
- Within the top 20 highest-cost injectable drugs, 71% of the cost is related to medications used to treat cancer. This includes all top five high-cost injectable drugs (Herceptin, Neulasta, Perjeta, Avastin, and Keytruda) and eight of the top 10.
- The number of members with claims over \$3 million doubled from 2017 to 2018. A primary driver of these large claims was prolonged hospital stays.
- In 2018, the largest claim was \$7.5 million. The largest claim for a single injectable drug was \$1.8 million.
- In a single policy year, 85% of employers were reimbursed for a stop-loss claim.



TOP 10 HIGH-COST CLAIM CONDITIONS

Total payments	Medical condition	2015–2018		2014–2017		Stop-loss claim reimbursements 2015–2018	
		Rank	Rank	Total reimbursements	% of total*	Total reimbursements	% of total*
31.3% Top 3 conditions	Malignant neoplasm (cancer)	1	1	\$674.0M	19.3%		
	Leukemia, lymphoma, and/or multiple myeloma (cancers)	2	2	\$262.3M	7.5%		
	Chronic/end-stage renal disease (kidneys)	3	3	\$159.3M	4.6%		
51.2% Top 10 conditions	Congenital anomalies (conditions present at birth)	4	4	\$141.9M	4.1%		
	Transplant	5	5	\$117.1M	3.3%		
	Septicemia (infection)	6	6	\$104.5M	3.0%		
	Liveborn**	7	9	\$93.7M	2.7%		
	Complications of surgical and medical care	8	7	\$89.9M	2.6%		
	Hemophilia/bleeding disorder	9	10	\$76.7M	2.2%		
	Cerebrovascular disease (brain blood vessels)	10	12	\$70.9M	2.0%		
Top 10 conditions						\$1.8B	51.2%
Total stop-loss reimbursements						\$3.5B	

*Percentage of total stop-loss claims reimbursements that Sun Life provided to its policyholders from 2014 to 2017.

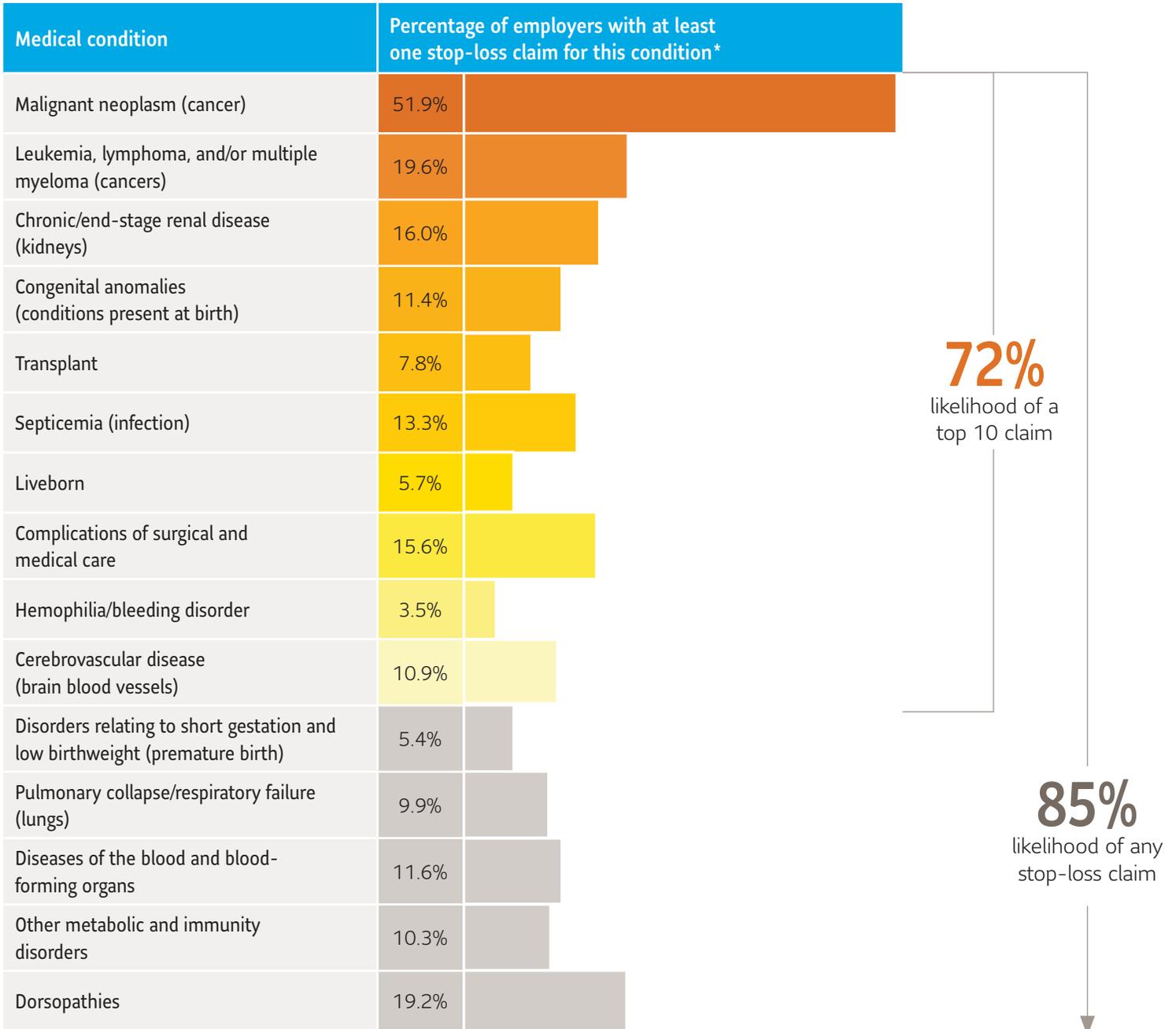
**When the Liveborn diagnosis becomes a high-cost claim, it is often accompanied by additional diagnoses. Please see page 4 for other conditions that may occur at the time of birth.

Source: Sun Life Financial book of business data, 2014–2018.

Likelihood of a stop-loss claim by condition

The likelihood of a self-funded employer having a stop-loss claim in any given policy year was 85%. However, the odds vary significantly based on condition. The top two claim conditions by cost, malignant neoplasm (cancer) and leukemia, lymphoma, and/or multiple myeloma (cancer), are also the two types of stop-loss claims an

employer is most likely to have. The third most likely stop-loss claim is for dorsopathies (spine), which is not included in the top 10 list. This is because the average cost of a dorsopathies claim is significantly lower than the cost of a cancer claim (\$57,990 versus \$143,065).



Methodology note: Employer reimbursement incidence reporting requires calculating claims on a policy-year basis. Likelihood represents the probability that an employer will experience a claim in any one policy year for each policy year from 2014–2017.

Top 10 claim conditions

The top 10 high-cost claim conditions represented 51.2% of all stop-loss claim reimbursements. From 2015 to 2018, conditions remained generally consistent for the top six positions, but the remaining four slots differ from those of last year's study, covering 2014–2017.

Cancer continues to hold the top two positions, accounting for 26.8% of all the total stop-loss claims and \$936.3 million in stop-loss reimbursements. Chronic/end-stage renal disease (kidneys) retained its #3 position. For the top three conditions, total stop-loss reimbursements increased by \$144 million to \$1.1 billion. But as a percent of stop-loss claims, they remained virtually the same, at 31.3%.

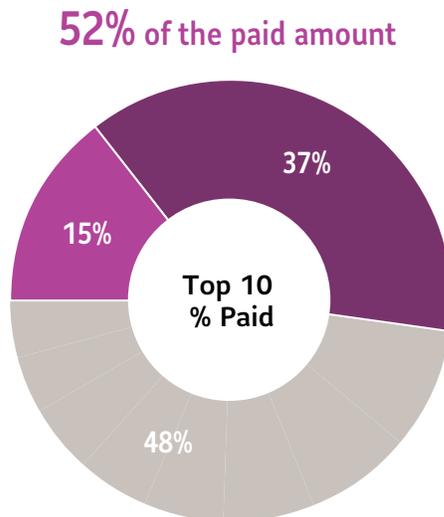
Liveborn climbed two spots since last year's study, to #7, while disorders relating to short gestation and low birthweight dropped out of the top 10, to #11. We continue to believe this shift is related to changes in the way birth-related claims are coded in ICD-10 reporting. Specifically, we believe that liveborn is chosen

as a primary diagnosis more often, with other related conditions selected as a second or third diagnosis. For example, conditions such as short gestation, low birthweight, and congenital anomalies, may be selected as a secondary diagnosis. Live births that do not occur with other conditions or complications generally do not result in a high-cost claim. However, the average cost for a claim for a liveborn from 2015–2018 that resulted in a stop-loss claim was \$347,589.

Hemophilia, which reached the top 10 for the first time in last year's study, rose again, to #9. Cerebrovascular disease/CVA was the only new condition to reach the top 10 in the 2015–2018 timeframe. Overall, stop-loss reimbursements are on the rise. From 2014 through 2017, in a single policy year, 85% of employers were reimbursed for a stop-loss claim, and 72% were reimbursed for a stop-loss claim in one of the top 10 claim conditions.

For the top 10 claim conditions, cancer accounts for:

- Malignant Neoplasm
- Leukemia, Lymphoma, and/or Multiple Myeloma
- Other top 10 conditions





Cancer remains the highest-cost condition

For the past several years, cancer has continually held top spot for the costliest claim condition. Cancer is defined as a disease that results when cellular changes cause the uncontrolled growth and division of cells.¹ Approximately 38.4% of people will be diagnosed with cancer at some point in their lifetime.² These diagnoses are spread across more than 100 different types of cancer. Some of the more common types of cancer are breast cancer, lung cancer, skin cancer, leukemia, colon cancer, and thyroid cancer.³ Qualifying a cancer as “common” requires over 40,000 cases or more at a given time.⁴

Overall, it was estimated that in 2018 over 1,730,000 total new cancer cases would be diagnosed in the United States.⁵ Considering breast cancer alone, approximately 1 in 8 women will develop invasive breast cancer in their lifetime.⁶ That means that in 2019, 271,270 new breast cancer cases are expected to be diagnosed in the U.S.⁷ In the analysis of 2015 to 2018 data, breast cancer was the most common type of cancer and also had the highest overall spend. Some of this cost is related to common treatments such as radiation and chemotherapy, but other cancer treatments are emerging that may point to changes in the cancer treatment landscape. We will explore some of these newer treatments later in this report.

1. Nall, Rachel. Medical News Today, Nov 2018, <https://www.medicalnewstoday.com/articles/323648.php>

2. National Cancer Institute, April 2018, <https://www.cancer.gov/about-cancer/understanding/statistics>

3. National Cancer Institute, February 2019, <https://www.cancer.gov/types/common-cancers>

4. Cancer.gov, February 2019, <http://www.cancer.gov/types/common-cancers>

5. National Cancer Institute, April 2018, <https://www.cancer.gov/about-cancer/understanding/statistics>

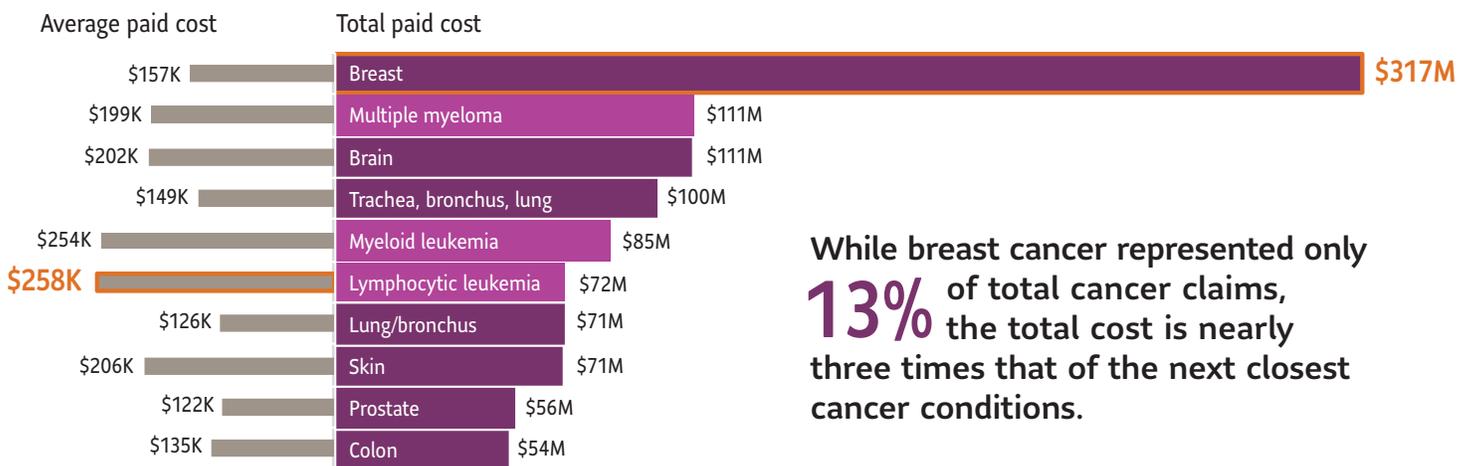
6. Breast Cancer.org, February 2019, https://www.breastcancer.org/symptoms/understand_bc/statistics

7. National Cancer Institute, February 2019, <https://www.cancer.gov/types/common-cancers>

While breast cancer had the highest frequency and highest total spend, the highest average spend over the same time period was for lymphocytic leukemia, at approximately \$258,000 per incidence. Lymphocytic leukemia is a type of cancer that starts in the bones but moves into the blood. The symptoms often take years to emerge as the cells often build up slowly before moving into other parts of the body such as the lymph nodes, liver and spleen.⁸

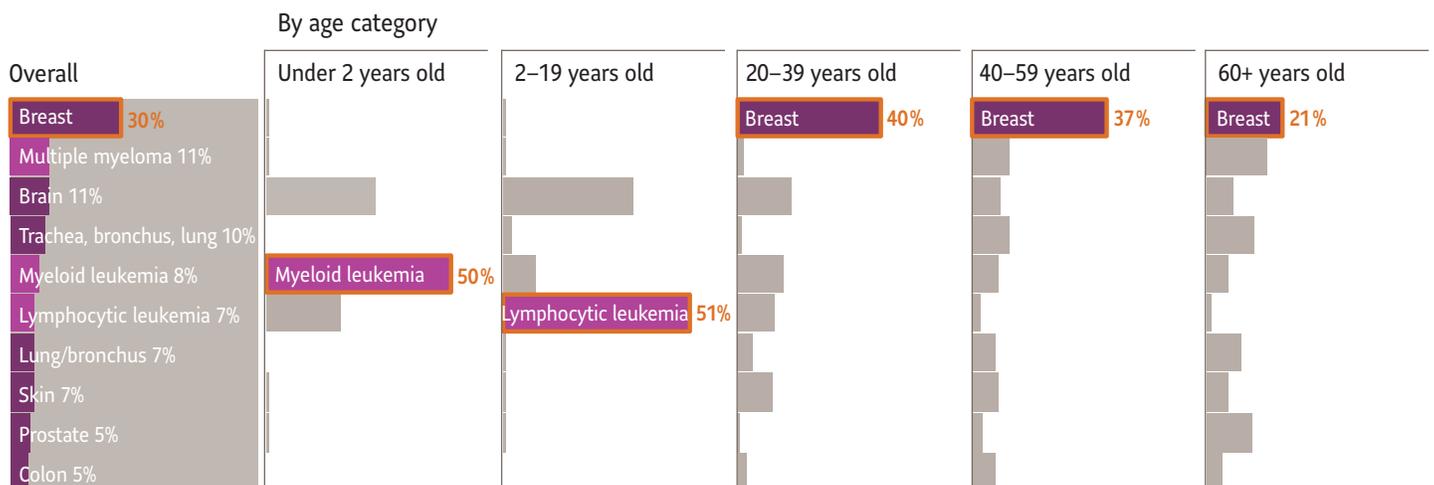
In terms of frequency (claim incidence), the top two claim conditions, both of which were cancer conditions, had a total count of over 14,500 individuals. This is more than the remaining eight conditions in the top 10 combined, with 9,500 individuals. Through this research and in-depth analysis of four years of claims data, we see that cancer is dominant, both in terms of the number of claims, and the total cost of treatment.

Top 10 cancer conditions



While breast cancer represented only **13%** of total cancer claims, the total cost is nearly three times that of the next closest cancer conditions.

Top 10 cancer conditions by age



8. American Cancer Society, May 2018, <https://www.cancer.org/cancer/chronic-lymphocytic-leukemia/about/what-is-cll.html>

Ten years of high-cost claim conditions

Medical condition	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2015–2018
Malignant neoplasm (cancer)	1	1	1	1	1	1	1	1	1	1	1
Leukemia, lymphoma, and/or multiple myeloma (cancers)	2	3	3	3	2	2	2	2	2	2	2
Chronic/end-stage renal disease (kidneys)	3	2	2	2	3	3	3	3	3	4	3
Congenital anomalies (conditions present at birth)	6	5	4	4	4	4	5	4	4	3	4
Transplant	5	11	15	17	10	5	4	5	5	7	5
Septicemia (infection)	13	9	12	10	11	7	7	6	6	6	6
Liveborn	14	18	9	9	20	14	13	7	8	5	7
Complications of surgical and medical care	12	6	6	13	13	9	12	8	7	9	8
Hemophilia/bleeding disorder	21	21	13	12	17	15	9	9	9	15	9
Cerebrovascular disease (brain blood vessels)	8	8	7	7	7	10	8	10	14	11	10
Disorders relating to short gestation and low birthweight*	4	4	5	6	5	6	6	13	11	25	11
Pulmonary collapse/respiratory failure (lungs)	11	7	11	8	9	8	10	14	10	17	12
Diseases of the blood and blood-forming organs	18	12	16	11	8	17	14	15	13	10	13
Other metabolic and immunity disorders	26	22	22	27	18	16	16	12	12	14	14
Dorsopathies	7	10	10	14	14	13	17	11	15	13	15
Congestive heart failure	9	15	8	5	6	11	11	17	20	19	16
Other	34	30	45	30	55	28	31	16	18	12	17
Unspecified procedures and aftercare	39	39	41	52	84	71	43	23	22	8	18
Cystic fibrosis	29	28	18	20	15	12	15	19	28	16	19
Mental disorders	112	69	65	43	38	20	25	20	16	20	20

Conditions over time

Based on stop-loss reimbursements, most conditions in the current top 10 list have appeared in the top 20 high-cost claim conditions over the past 10 years. We have collected data from our past research reports to show how some conditions remain constant while others move over time.

*Disorders relating to short gestation and low birthweight is also referred to as premature birth

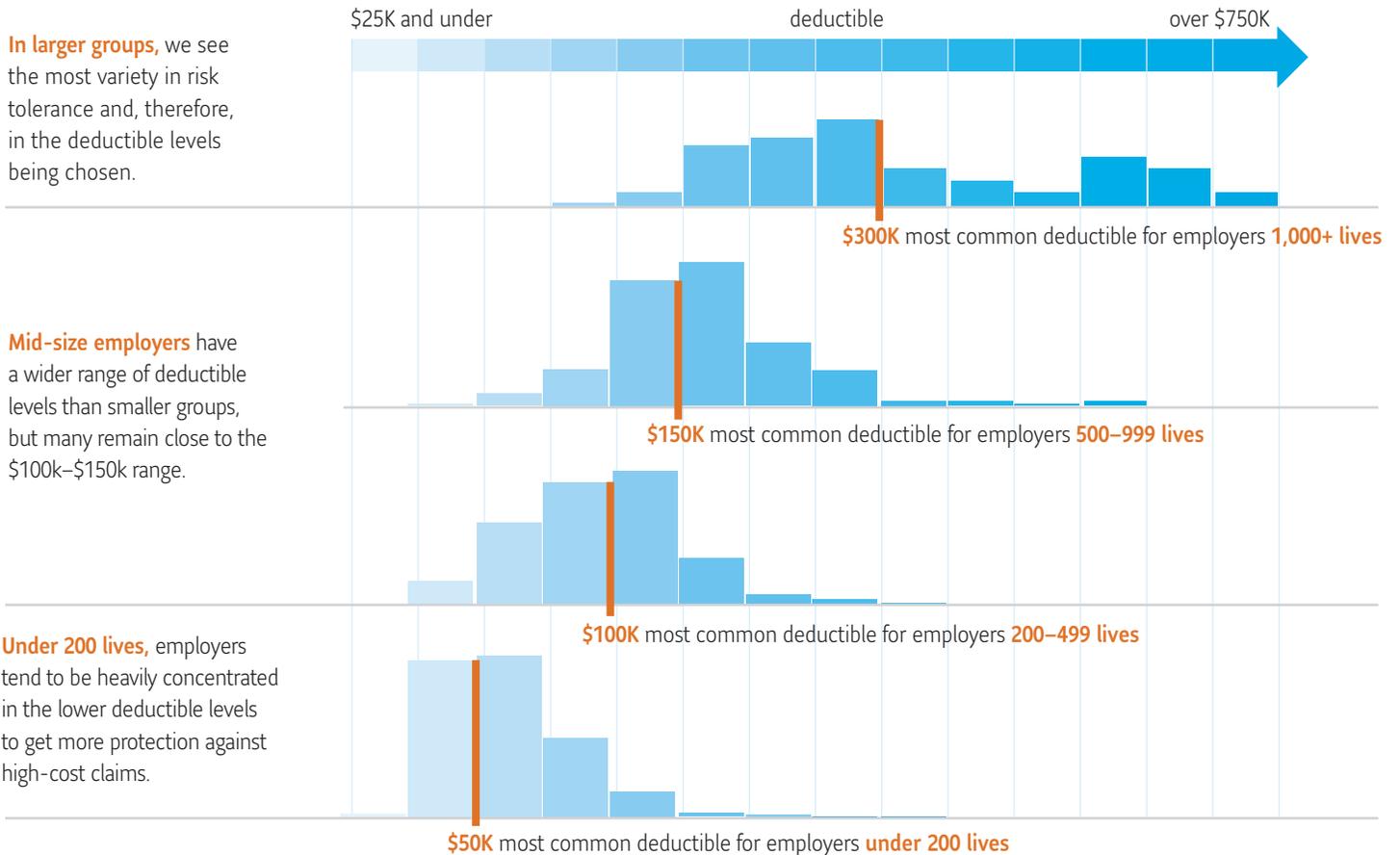
Source: Sun Life Financial book of business data, 2009–2018.

Top 10 high-cost conditions by deductible level

Stop-loss deductibles by case size

Employers have options when it comes to selecting a deductible level for their group. Typically, larger employers are more comfortable taking on more risk by choosing a higher deductible. Smaller groups tend to choose lower deductible levels with less risk and higher premiums. Because deductible levels vary, different claim conditions are more or less likely to hit the deductible and become a stop-loss claim. This data may be particularly useful for employers as they consider what conditions are likely to result in a stop-loss claim based on their

deductible selection. While the overall top 10 conditions list includes all of our high-cost claims across geographies, industries, deductible levels and age, it is important to note how the top 10 conditions change based on stop-loss deductible level. The conditions noted on the following page in blue or gray appear in the top 10 for a particular deductible level, but do not appear in the overall top 10 list. The conditions that appear in the top 10 list at lower deductibles tend to be conditions that don't cost enough to exceed the higher deductible levels.



Source: Sun Life Financial book of business data, 2015-2018.

Top 10 high-cost claim conditions by deductible level

Top 10
 11–20
 Not in top 20

Rank	Overall	\$0–50K	\$51K–100K	\$101K–250K	\$251K–500K	\$500K+
1	Malignant neoplasm	Congenital anomalies				
2	Leukemia, lymphoma and/or multiple myeloma	Dorsopathies	Leukemia, lymphoma and/or multiple myeloma	Leukemia, lymphoma and/or multiple myeloma	Leukemia, lymphoma, and/or multiple myeloma	Transplant
3	Chronic/end-stage renal disease	Leukemia, lymphoma and/or multiple myeloma	Chronic/end-stage renal disease	Chronic/end-stage renal disease	Congenital anomalies	Malignant neoplasm
4	Congenital anomalies	Chronic/end-stage renal disease	Congenital anomalies	Congenital anomalies	Transplant	Hemophilia/bleeding disorder
5	Transplant	Mental disorders	Dorsopathies	Liveborn	Chronic/end-stage renal disease	Pulmonary collapse/respiratory failure
6	Septicemia	Septicemia	Septicemia	Septicemia	Septicemia	Leukemia, lymphoma and/or multiple myeloma
7	Liveborn	Coronary Atherosclerosis	Cerebrovascular disease	Transplant	Liveborn	Congestive heart failure
8	Complications of surgical and medical care	Congenital anomalies	Complications of surgical and medical care	Complications of surgical and medical care	Disorders relating to short gestation and low birthweight	Septicemia
9	Hemophilia/bleeding disorder	Cerebrovascular disease	Liveborn	Hemophilia/bleeding disorder	Complications of surgical and medical care	Other respiratory conditions of fetus and newborn
10	Cerebrovascular disease	Other	Other	Cerebrovascular disease	Hemophilia/bleeding disorder	Respiratory distress syndrome, fetus or newborn

Notable deductible level differences

- Two conditions only appear in the top 10 for deductibles under \$50,000: mental disorders and coronary atherosclerosis (ASHD). More than half of Americans are diagnosed with a mental disorder at some point in their life.⁹
- Dorsopathies, a frequent but lower-cost condition related to the spine, appears in the top 10 for deductible levels under \$100K only.
- Both transplant and hemophilia/bleeding disorder (a disorder that prevents blood from clotting normally) appear in the top 10 only if the deductible is over \$100,000.
- Cerebrovascular disease/CVA drops out of the top 10 once the deductible level is over \$250,000.
- Four conditions only appear in the top 10 with deductibles of \$500,000 or more: Pulmonary collapse/respiratory failure, congestive heart failure, and two conditions related to respiratory conditions or distress of a fetus or newborn.
- Malignant neoplasm (cancer) is the top condition across all deductible levels, except for the \$500,000+ deductible group, where congenital anomalies are the costliest conditions.

Source: Sun Life Financial book of business data, 2015–2018.

9. Medline Plus, February 2019, <https://medlineplus.gov/mentaldisorders.html>



TOP 20 HIGH-COST INJECTABLE DRUGS

2015 Rank	→	2018 Rank	Injectable drug	Paid charges	Average paid charges	Most frequently used to treat
1		1	Herceptin	\$17.4M	\$95.4K	Cancer
2		2	Neulasta	\$16.4M	\$35.7K	Cancer
3		3	Perjeta	\$10.9M	\$86.3K	Cancer
4		4	Avastin	\$10.7M	\$59.7K	Cancer
5		5	Keytruda	\$10.1M	\$113.3K	Cancer
6		6	Opdivo	\$9.2M	\$96.8K	Cancer
7		7	Soliris	\$8.7M	\$457.2K	Blood disorder
8		8	Yervoy	\$8.5M	\$198.5K	Cancer
9		9	Rituxan	\$7.0M	\$50.1K	Cancer
10		10	Advate, Kogenate*	\$6.5M	\$363.9K	Blood disorder
		11	Uncategorized Drugs	\$5.9M	\$9.7K	Other
		12	Spinraza	\$5.7M	\$332.5K	Other
		13	Inflectra, Remicade	\$4.9M	\$55.9K	Other
14		14	Eloctate	\$4.4M	\$629.8K	Blood disorder
15		15	Darzalex	\$4.1M	\$107.2K	Cancer
		16	Alimta	\$3.7M	\$60.6K	Cancer
		17	Gammagard	\$3.5M	\$84.5K	Other
18		18	Velcade	\$3.3M	\$44.4K	Cancer
19		19	Tysabri	\$3.3M	\$110.0K	Other
		20	Adcetris	\$3.3M	\$192.1K	Cancer
			Totals			
			Top 20 by type	\$104.5M	\$69.5K	Cancer
				\$19.6M	\$446.5K	Blood disorder
				\$23.3M	\$29.7K	Other
			Overall top 20	\$147.4M		
			All injectables	\$252.6M		

*Additional brand names are associated with this medication.

Source: Sun Life Financial book of business data, 2015–2018.

Injectables (IV and self-administered injectable medications) tracked in the study had a significant impact on claim costs. From 2015 to 2018, paid charges for injectable drugs were 9.2% of the total paid charges for high-cost claims. Injectable drugs have represented about 9% of total paid claims for the past four years, reaching a high of 10.9% in 2018. Forty-five percent of that overall cost was reimbursed to employers under their stop-loss coverage.

In 2018, 561 drugs contributed to the total \$252.6 million that was spent on injectable medications. Eighty-eight percent (or \$147.4 million) was attributed to the top 20 injectable medications and, in fact, 26% of the cost was related to just the top five. All of the top five high-cost injectable drugs (Herceptin, Neulasta, Perjeta, Avastin and Keytruda) are most frequently used to treat cancer.

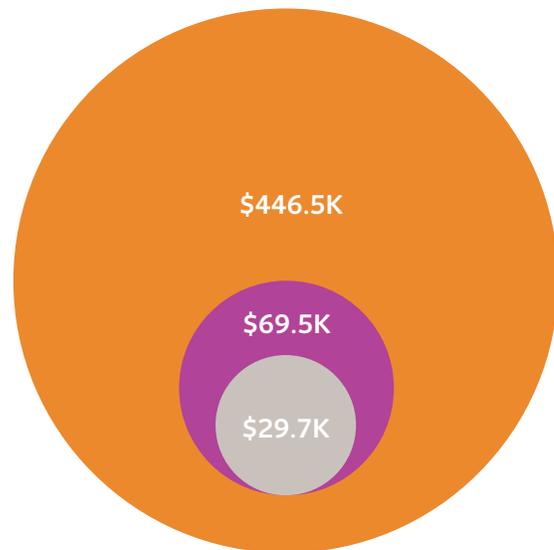
Impact of injectable drugs

Injectable drug costs were **9.2%** of total paid claims

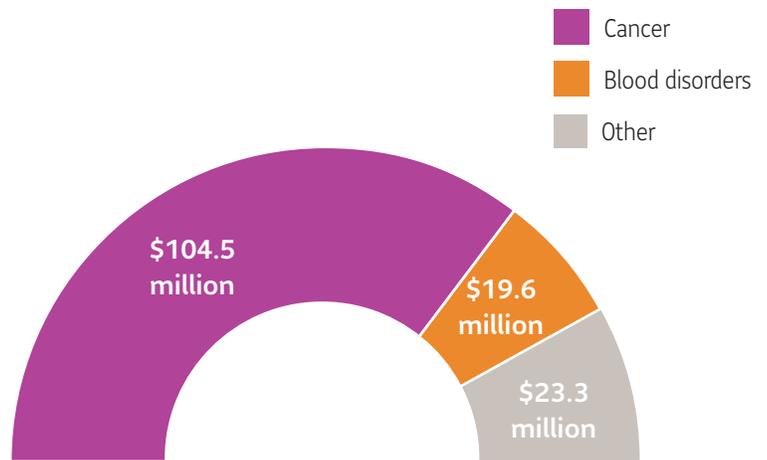


2018 Top 20 high-cost injectable drugs: average cost versus total cost

Average paid charges by category



Total paid charges by category



Source: Sun Life Financial book of business data, 2015–2018.

Conditions that high-cost injectables treat

Cancers are the #1 (malignant neoplasm) and #2 (leukemia, lymphoma and/or multiple myeloma) high-cost claim conditions. Chemotherapy drugs, or drugs given in conjunction with chemotherapy, are frequently used to treat cancer. Eight of the top 10 high-cost injectable drugs were used to treat a cancer condition, including all of the top five. The average paid charge associated with an injectable drug used in cancer treatment is relatively low, at about \$43,000. However, these drugs are used so frequently that they make up 71% of the top 20 injectable drug costs, totaling \$104.5 million in 2018.

Injectable drugs are also used to treat blood disorders such as hemophilia and paroxysmal nocturnal hemoglobinuria. The three medications related to blood disorders in the top 20 drugs were used to treat 163 people in 2018, compared to 2,548 people who were treated for cancer. However, their average paid

charge was much higher, at approximately \$446,500. Overall, treatment for blood disorders contributed to \$19.6 million (or 13%) of the top 20 injectable drug cost in 2018.

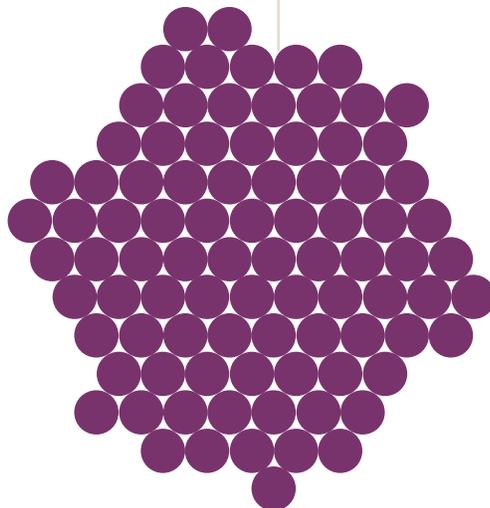
Frequency versus severity

Some injectables generate high costs because they are frequently prescribed, even if their average cost is relatively low. Others generate high costs based on the medications high average cost, even if fewer people use it. For example, two medications used during treatment of cancer, Keytruda and Neulasta, are among the top five injectable drugs. Neulasta (approved to reduce the chance of infection in patients undergoing chemotherapy) was used by 460 patients and had an average cost of \$35,700. In contrast, Keytruda, approved for treatment of a variety of cancer conditions, was used by only 89 patients but its average cost was higher, at about \$113,300.

Reaching the top five: frequency versus severity

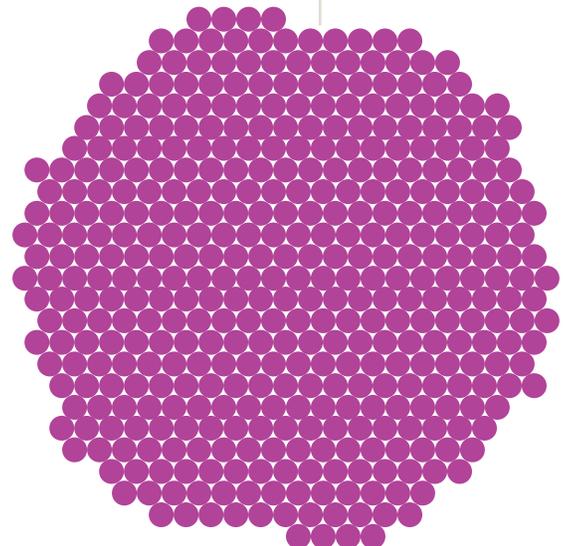
Keytruda \$10.1M

89 claimants
\$113.3K per claimant



Neulasta \$16.4M

460 claimants
\$35.7K per claimant





Looking ahead

Legislative updates

While the Affordable Care Act (ACA) passed its ninth anniversary on March 22, the future of the law remains in question. With the individual mandate penalty reduced to \$0 as of January 1, 2019, the State of Texas has led a lawsuit arguing that this change means the entire ACA is no longer constitutional. In December 2018, a District Court agreed with this argument and the case is now making its way through the appeals process. Should the District Court's decision be upheld, all of the ACA's requirements, regulations, taxes and fees would no longer be applicable. If this case is eventually taken up by the Supreme Court, a final decision might not be reached until early 2020.

Separately, the Administration and Congress are working to provide drug pricing transparency and put more consumer cost protections in place. Both the House and the Senate have held a number of hearings involving the CEOs of pharmaceutical companies as well as Pharmacy Benefit Managers (PBMs). Once these hearings are completed, both the House and Senate will likely introduce legislation aimed at reducing prescription

drug prices. Additionally, members of both parties are introducing proposals to end the practice of patient balance billing for out-of-network emergency care.

Emerging therapies

Gene therapies target diseases resulting from faulty genes by creating a working version for the body. These therapies are a focal point in the industry due to their ability to cure devastating diseases, possibly in a single treatment. They are also an area of interest based on their high price-tag. Luxturna, used to treat a rare form of genetic eye disorder that can cause blindness,¹⁰ was the only gene therapy available in the U.S and Europe¹¹. Recently, Zolgensma was approved as a cure for spinal muscular atrophy, a disease that in its most severe form affects approximately 300 American infants per year and is typically fatal. Novartis has set the price of the drug at \$2.125 million per patient.¹² The FDA expects to approve between 10 and 20 gene and cell therapies a year by 2025.¹³

10. Spark Therapeutics, 2018, <https://luxturna.com/about-luxturna/>

11. Spark Therapeutics, Inc., Nov 2018, <http://ir.sparktx.com/news-releases/news-release-details/european-commission-approves-spark-therapeutics-luxturna>

12. Stein, Rob, NPR, May 2019, <https://www.npr.org/sections/health-shots/2019/05/24/725404168/at-2-125-million-new-gene-therapy-is-the-most-expensive-drug-ever>

13. U.S. Food and Drug Administration, January 2019, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics>

Cancer drugs on the rise

Medications play a significant role in cancer treatment for the 38.4% of people who will be diagnosed with cancer at somepoint in their lifetime.¹⁴ In fact, our data from 2018 indicates that 8 of the top 10 high-cost injectable medications were used in the treatment of cancer. The following section includes a closer look at five notable cancer drugs from this year's top 20 high-cost injectable drugs list.

Herceptin – Holding the #1 spot

Herceptin was the overall highest-cost injectable drug in 2018. Herceptin is a therapy designed to help fight HER2+ breast cancer, an aggressive form of cancer in which cells have too many HER2 receptors, causing the cells to grow and divide too quickly. Since its approval in 1998, Herceptin's

use has expanded to also treat early-stage breast cancer that is HER2+, and stomach cancer.¹⁵ It can be used in a variety of ways, including with certain chemotherapy drugs or alone after treatment.¹⁶

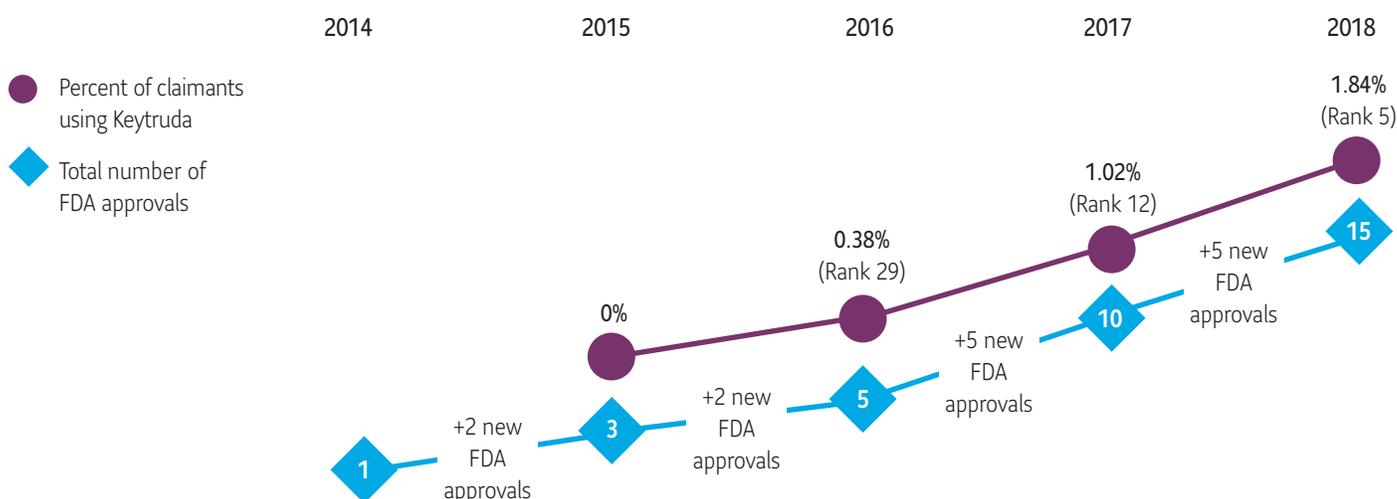
Perjeta – Rising to #3

Perjeta is an injectable drug first released in 2012 by the U.S. Food and Drug Administration as a new therapy designed to treat metastatic breast cancer. In 2013, the FDA approved an additional use for Perjeta for early-stage breast cancer, and uses continued to expand.¹⁷

Keytruda – Rapid expansion

Keytruda, this year's fifth highest-cost injectable drug, works as a checkpoint inhibitor by placing markers on certain cells to activate an immune

Evolution of a drug: Keytruda¹⁸



Keytruda was originally approved for advanced melanoma in 2014. Since then, it has received additional FDA approvals every year, including approval to treat some forms of lung and cervical cancers. By the end of 2018, Keytruda had received 15 total FDA approvals. From 2015 to 2018, Keytruda also rose in the ranks of our most costly injectable drugs, from zero use in 2015 to the fifth most costly drug in 2018, used by 1.84% of claimants with injectable drug spend.

14. National Cancer Institute, April 2018, <https://www.cancer.gov/about-cancer/understanding/statistics>

15. Nordqvist, Christian, 2019, Medical News Today, <https://www.medicalnewstoday.com/articles/173486.php>

16. Genetech, USA, 2019, <https://www.gene.com/patients/medicines/herceptin>

17. U.S. Food and Drug Administration, December 2017, <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-regular-approval-pertuzumab-adjuvant-treatment-her2-positive-breast-cancer>

18. Drugs.com, 2019, <https://www.drugs.com/history/keytruda.html>

system response.¹⁹ Demand for checkpoint inhibitors like Keytruda is on the rise.²⁰ As an immunotherapy, Keytruda works with the immune system to help fight cancer.²¹ Keytruda was originally approved for treatment of advanced melanoma in 2014. It is now prescribed for a variety of cancers. Marketing efforts directed towards consumers have been heavy for this drug, with over \$5.9 million spent on commercials targeting patients.²²

Adcetris – New to top 20

Adcetris, a drug used to treat adults with classical Hodgkin's lymphoma and T-cell lymphoma, is of particular interest due to its emergence onto this year's top 20 list. Adcetris represents a different kind of cancer treatment that works by using cell-killing agents that target cancer cells without damaging normal cells, which minimizes side effects for the patient without compromising effectiveness.²³ Since its approval in 2011, Adcetris has expanded from its original use (treating two types of lymphoma) to now treating types of large cell lymphoma, other variations of Hodgkin's lymphoma, as well as other forms of cancer.²⁴

Darzalex – Accelerated approval

Darzalex is a prescription medicine used to treat only a specific type of blood cancer called multiple myeloma. Darzalex is not a chemotherapy. It is a targeted monoclonal antibody that helps slow or stop the progression of multiple myeloma in several ways by attaching itself to multiple myeloma cells in the body, killing the cell or allowing the immune system to destroy it.²⁵ Darzalex was approved under the agency's accelerated approval program in late 2015.²⁶ This program allows the approval of a drug to treat serious illnesses that show a reasonable likelihood of producing clinical benefits for patients.²⁷

Looking ahead: Cancer

The outlook and landscape for those diagnosed with cancer is changing. By 2026, the number of cancer survivors is expected to increase by 31%.²⁸ Focus has been placed on targeted therapies, which aim to go after the cancer cells more directly, while doing less damage to healthy cells, and on immunotherapy, which uses the body's immune system to fight off the cancerous cells.²⁹ In each of these treatment areas, several new drugs are being explored that may work for specific variations of the disease. These new therapies, in addition to the expanded use of existing drugs to treat additional types of cancer, are areas to keep an eye on in the future.

19. Cancer.org, October 2018, <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/immune-checkpoint-inhibitors.html>

20. *Microsoft News*, March 2019, <https://www.msn.com/en-us/money/topstocks/mercks-keytruda-picks-up-pace-in-thriving-anti-pd-l1-market/ar-BBV3wkM>

21. Keytruda, 2019, <https://www.keytruda.com/how-does-keytruda-work/>

22. Bulik, Beth Synder, FiercePharma, September 2017, <https://www.fiercepharma.com/marketing/new-merck-tv-ad-for-keytruda-continues-tru-theme-but-now-features-real-patient>

23. Cancer.org, May 2019, <https://www.cancer.org/cancer/hodgkin-lymphoma/treating/monoclonal-antibodies.html>

24. Drugs.com, 2019, <https://www.drugs.com/history/adcetris.html>

25. Janssen Biotech, Inc., March 2019, <https://www.darzalex.com/multiple-myeloma-treatment/what-is-darzalex>

26. American Health & Drug Benefits, February 2019, <http://www.ahdbonline.com/web-exclusives/2020-fda-approves-darzalex-for-patients-with-previously-treated-multiple-myeloma>

27. *Pharmacy Times*, November 2017, <https://www.pharmacytimes.com/contributor/ryan-chandanais-ms-cphd/2017/11/a-look-at-the-fdas-accelerated-approval-program>

28. National Cancer Institute, April 2018, <https://www.cancer.gov/about-cancer/understanding/statistics>

29. American Cancer Society, December 2018, <https://www.cancer.org/latest-news/2018-in-review-new-cancer-drug-approvals.html>

Million-dollar+ claim trends

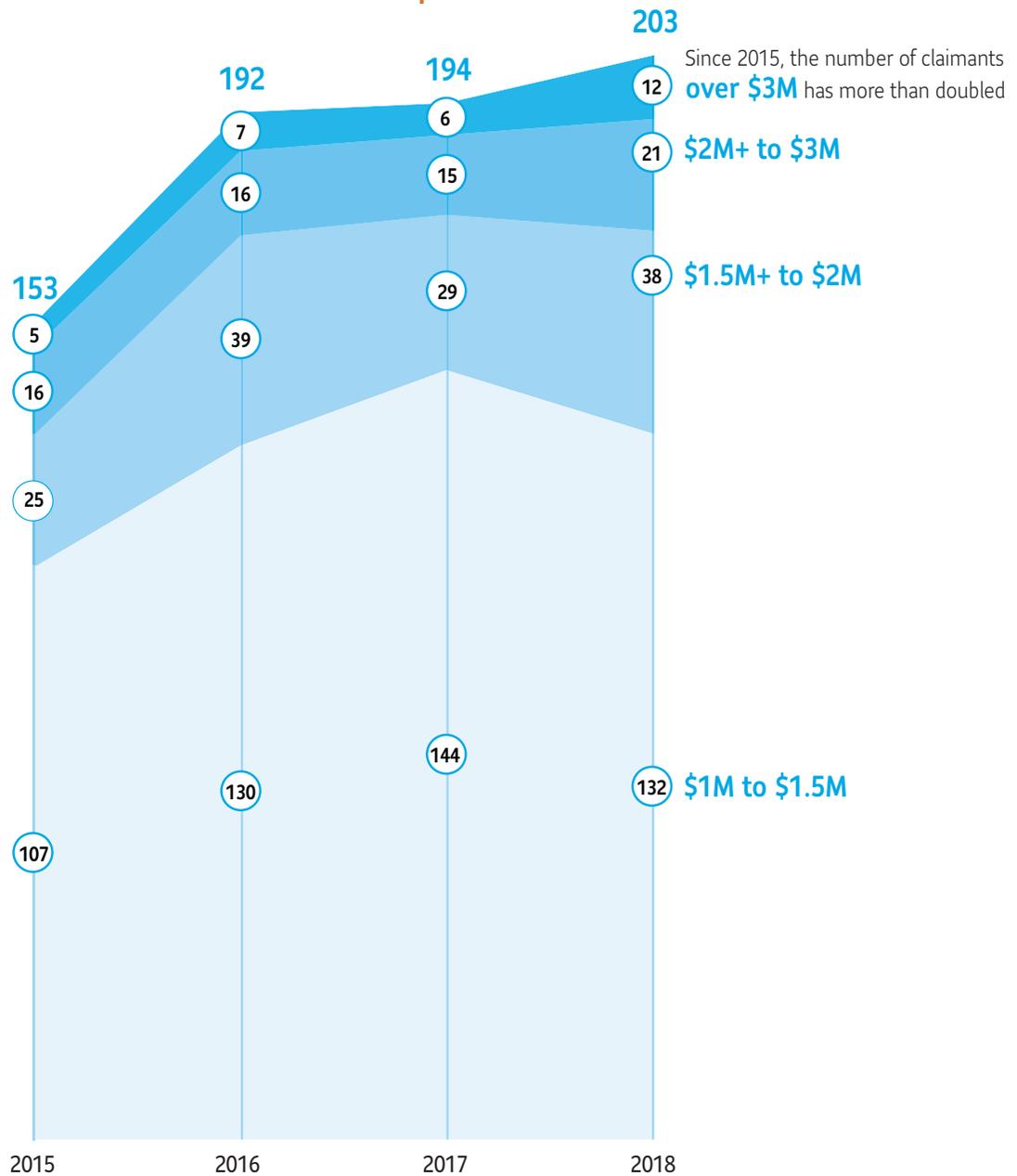
Prevalence of \$1M+ claims

From 2015 to 2018, 22% of employers had at least one member with claims over \$1 million.

Between 2015 and 2018, 742 individuals had claims exceeding \$1 million dollars in a single policy year. The average paid amount of a \$1 million+ claim was \$1.5 million. Claims between \$1 million to \$1.5 million also had the highest claim count. However, this category did not see the biggest jump on a percentage basis. During this same time frame, there was a 54%

increase in claims of \$1.5 million and above. Looking at the change from 2017 to 2018 alone, the number of \$3 million+ claimants doubled. Members with more than \$1 million in claims represented only 2.0% of individuals whose claims led to a stop-loss reimbursement, but they were 21% of total stop-loss claims reimbursement dollars (\$735.5 million).

Total claimants with \$1M+ in paid claims



Source: Sun Life Financial book of business data, 2015–2018.

Conditions most likely to result in \$1 million+ claims

During 2015–2018, the top five highest-cost million-dollar conditions were malignant neoplasm (cancer), congenital anomalies (conditions present at birth), leukemia, lymphoma, and/or multiple myeloma (cancers), transplant, and hemophilia/bleeding disorder. The higher frequency of the cancer conditions increased the overall likelihood that they would produce million-dollar+ reimbursements. Congenital anomalies, transplants and hemophilia/bleeding disorders are less frequent, but tend to be more costly.

In 2018 alone, there were 12 members with claims over \$3 million. Considering the diagnosis with the highest costs for each individual, four were mainly

related to a transplant (including three heart and lung transplants), four were related to congenital anomalies, and four were driven by cancer-related treatments (including high-cost chemotherapy). It is important to note that none of these conditions are considered rare. Conditions occurring together (comorbidities) and complications can increase the cost of treatment. The majority of these patients had some combination of complicated procedures, advanced life-sustaining treatments and/or other complications that required long in-patient stays. A main driver of these large claims was prolonged hospital stays, including hospital stays up to 347 days during 2018.

Individuals with largest claims in 2018



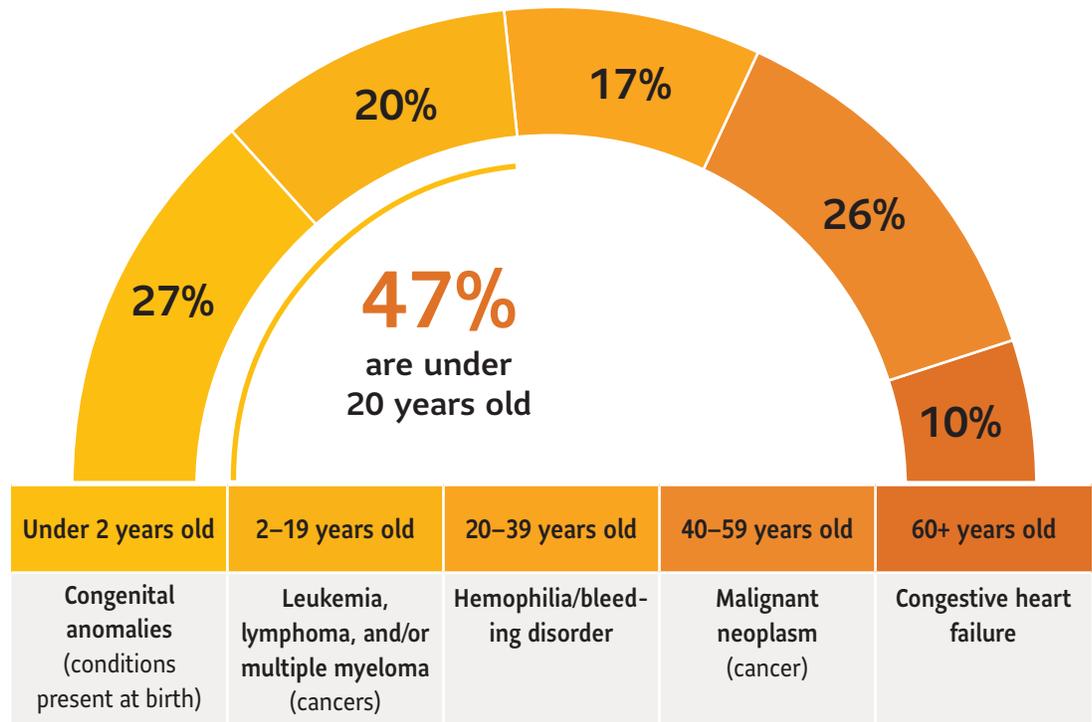
Source: Sun Life Financial book of business data, 2015–2018.

Impact of member age on million-dollar+ claims

A significant portion of members with the highest claim cost were children. Twenty-seven percent of people with claims of a \$1 million or more were under age two, and 47% were under age 20. For those under age two, the leading high-cost claim condition was congenital anomalies (children with conditions present at birth). Cancer was the most common million-dollar claim category for ages 2–19 (leukemia, lymphoma and multiple myeloma) and ages 40–59 (malignant neoplasm). Hemophilia was the leading claim condition for people between the ages of 20 and 39. Only 10% of the members with more than \$1 million in claims were over age 60. For that age range, the leading high-cost claim condition was congestive heart failure.



Individuals with million-dollar+ claims by age



Leading high-cost condition

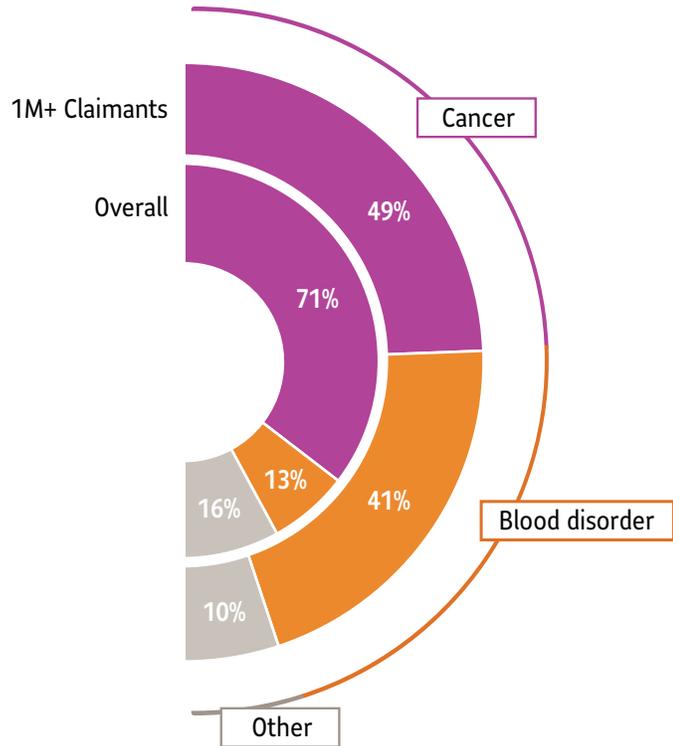
Source: Sun Life Financial book of business data, 2015–2018.

High-cost injectables for million-dollar+ claims

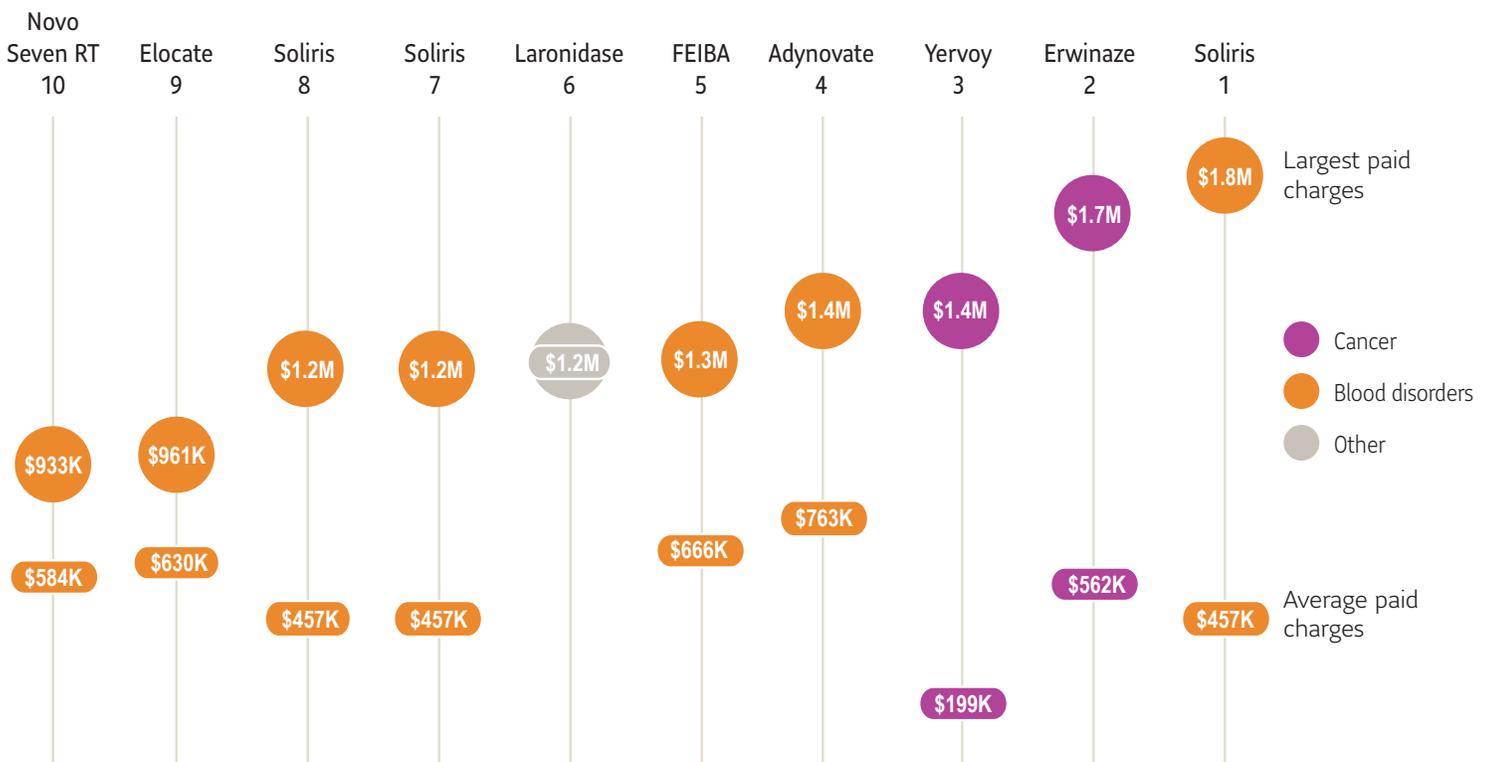
High-cost intravenous medications can significantly affect the overall cost of the most expensive claims. Multiple conditions occurring at the same time, complex medical treatment plans, and rare conditions that require specialty medications can result in claims that reach \$1 million or more.

Our data shows that in 2018, the top 20 highest-cost injectables used for treating members with more than \$1 million in claims was different from the overall top 20 list. Also, injectable drug costs associated with blood disorders made up a greater percentage of the costs for \$1M+ claims (41%), compared to the overall top 20 high-cost drug list (13%). In 2018, eight members exceeded \$1 million in claims with a single drug.

Injectable drug costs



Members with the highest injectable drug cost for a single drug in 2018



Source: Sun Life Financial book of business data, 2018.

The importance of stop-loss coverage

High-cost claims are not always predictable. Stop-loss insurance reimburses the employer for the portion of the claim that exceeds the stop-loss deductible, and it is a critical consideration for self-funded employers in limiting the risk associated with their medical plan. When looking into stop-loss options, consider the following:

- **Evaluate** the stop-loss coverage and decide if the right coverage is in place. Consider risk tolerance, claims experience, and peer benchmarks when selecting or changing the stop-loss deductible level.
- **Include** pharmacy claims in your stop-loss coverage.
- **Ask** about additional options to increase renewal rate predictability.
- **Ensure** your stop-loss carrier has clinical resources available to work with claims administrators and cost-containment vendors in order to identify opportunities for cost savings.
- **Consider** adding stop-loss coverage on large self-funded employers who have not purchased it in the past.

Likelihood of a stop-loss claim

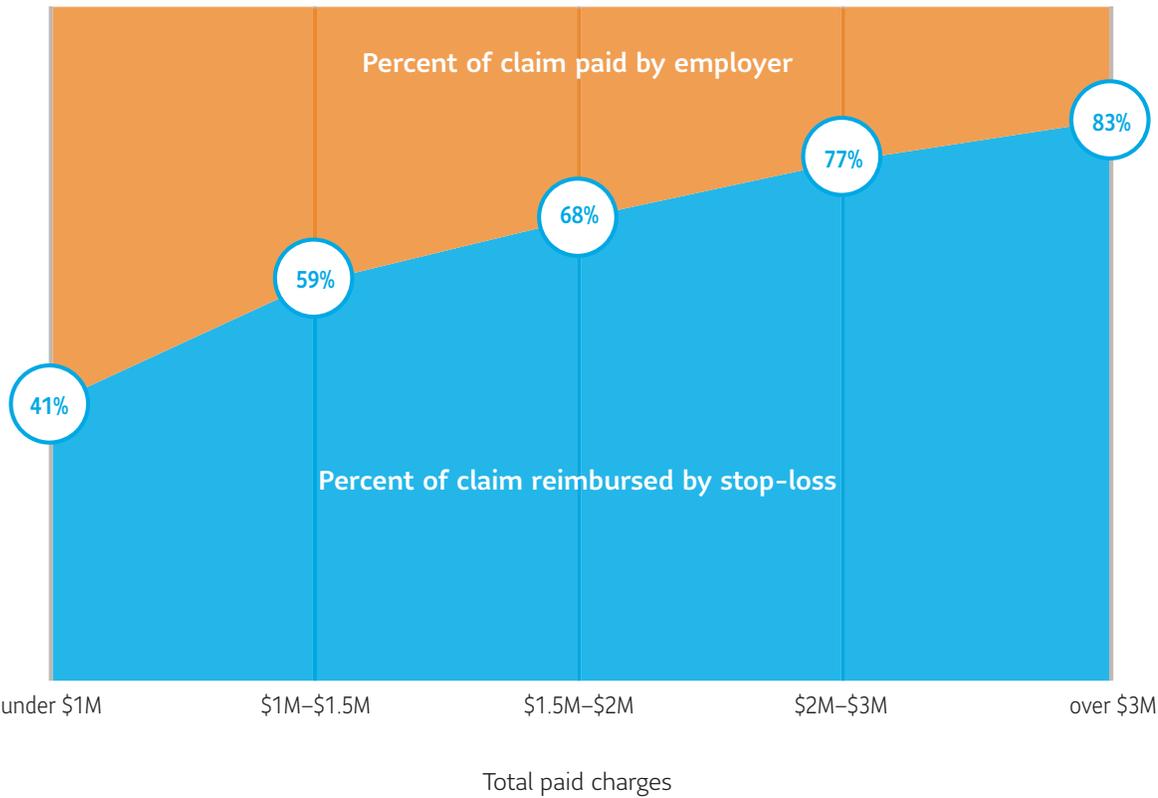
84% of employers had a stop-loss claim during the 2017 policy year

A \$1M+ claim	4.4%
A birth-related stop-loss claim	20.1%
A cancer stop-loss claim	57.9%
An injectable drug stop-loss claim	64.9%
Any stop-loss claim	84.4%





Percent of claims over \$1 million covered by stop-loss



Source: Sun Life Financial book of business data, 2015-2018.

Recommendations

Consider using any of the recommendations below for the high-cost claim conditions and injectable drug trends that we've highlighted in this report.

Medical



- **Determine** which medical conditions are having the largest impact on the plan's medical expenses.
- **Understand** which high-cost conditions are likely to occur based on the demographics of the group, including those that may require complex treatments or high-cost medications.
- **Confirm** that your administrator has internal or external utilization review, case management and negotiation services available to assist with ongoing high-cost claims.
- **Check** with the current or proposed claim administrator and stop-loss carrier to find out if clinical resources are available to identify opportunities for cost savings, and ask about any vendor relationships that may provide additional negotiation support or additional high-quality care options.
- **Ensure** utilization of clinical resources for premature infants, heart conditions, congenital anomalies, transplants, and cancer treatments (including emerging gene therapies).
- **Validate** that your administrators and your stop-loss carrier have the clinical resources to ensure high-quality care and have the ability to identify and assist in mitigating financial risk.
- **Consider** using plan document professionals to evaluate your entire plan document annually.
- **Review** your case management and wellness strategy for programs and support for plan members who are or may become pregnant. Check to see if your administrator has a high-risk pregnancy program available.
- **Review** your case management and wellness strategy for programs and support for plan members who are diagnosed with blood disorders. Ask your Pharmacy Benefit Manager (PBM) whether or not they have programs to support patients who are diagnosed with high-cost treatment conditions.
- **Consider** adding critical illness coverage option to your benefit plan to help employees

financially protect themselves in the event of a critical illness diagnosis. Associated benefits help to cover the additional care needs outside of traditional treatment costs that you may incur (transportation, additional care, childcare, specialty clothing, lodging, nutritional needs, etc.)

Rx



- **Review** claim history to determine which medications have the largest impact on the plan's medical expenses. Analyze the current use of specialty medications. Be sure to identify medication expenses that come through the medical plan as well as those associated with the pharmacy benefit.
- **Monitor** the introduction and expansion of gene therapies to determine cost trends. Both your medical plan and PBM should advise you on plan and formulary recommendations.
- **Ask** the PBM how they manage high-dollar medications and their approach to mitigating financial risk.
- **Evaluate** the definition of "specialty drugs" in the plan document for potential changes..
- **Ask** your administrator or PBM what programs are in place for high-cost drugs; that includes prior authorization, split fill, step therapy, tiering, and any programs for specialty drug management.
- **Review** your plan language to see if it includes provisions to support drug infusions or treatments delivered at home rather than at a facility, reducing costs while also providing a comfortable environment for the patient.
- **Check** in with your PBM about emerging changes in costs and patient care through pipeline reports and trend data. Stay informed about new and emerging treatments, as well as changes in approved uses for specific medications. Determine whether adjustments to the plan language should be made.

About the study

Sun Life conducted an internal aggregate analysis of its stop-loss claim conditions and associated costs from 2015 to 2018.

Methodology

For all reporting, except employer reimbursement incidence, the claims data included specific stop-loss claims paid as of December 31 for each year from 2015 to 2018. From a data perspective, the impact on the analysis due to policy reimbursement caps or lasing was not significant. Because employer reimbursement incidence reporting requires calculating claims on a policy-year basis, the claims data for employer reimbursement incidence were derived from stop-loss claims reimbursements that applied to the stop-loss policy years beginning with 2014 and ending with 2017. Members who breached the \$1 million threshold were determined using all paid claims dollars (below and above the stop-loss deductible) attributable to that claim during

the calendar year – January 1 to December 31 for each year from 2015 to 2018. Rounding was done on a “to nearest” basis.

Claim conditions categories

To create conditions categories, Sun Life reviewed all claim conditions and combined similar conditions and billing categories.

Data demographics

The claims data were from Sun Life stop-loss policyholders with approximately 50 to over 100,000 employees across the United States. The case size of these policyholders was determined by counting the number of employees covered by the stop-loss policy.

Sun Life stop-loss book of business

2,300
policyholders



\$1.6B
in premium



\$3.5B
stop-loss claim
reimbursements
(2015 through 2018)



4.7M
covered lives



\$7.9B total spent on
high-cost conditions:
first-dollar stop-loss claims payments
and stop-loss claims reimbursements
(2015 through 2018)



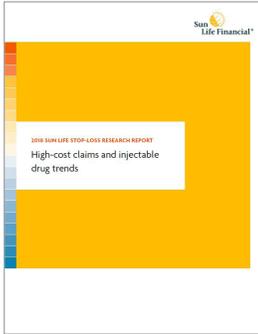
Top 20 primary industries for participating policyholders

Rank	Industry
1	Health and hospitals: hospitals, general, medical, surgical
2	Education: elementary and secondary schools
3	Public/government: executive offices
4	Education: colleges and universities
5	Specialty hospitals other than psychiatric
6	Hotels, motels and tourist courts
7	Skilled nursing-care facilities
8	Grocery stores
9	Wholesale and retail trade: catalogue and mail order houses
10	Engineering services
11	Trucking other than local
12	Offices and clinics of doctors of medicine
13	Management services
14	Management investment offices
15	Health and allied services
16	Management consulting services
17	Insurance agents, brokers, and service
18	Business services
19	Religious organizations
20	Schools and educational services

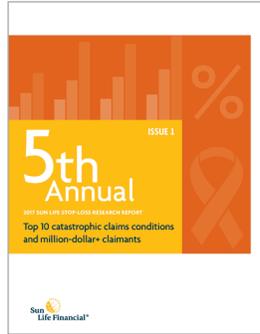


A library of resources

For additional insights, take a look at some of our other reports in our library.



2018 Stop-Loss Research Report



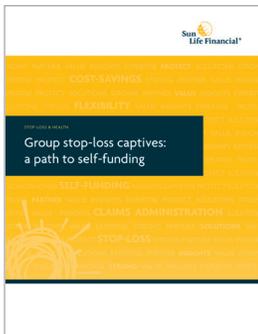
2017 Stop-Loss Research Report, Issue 1



2017 Stop-Loss Research Report, Issue 2



Self-funded playbook



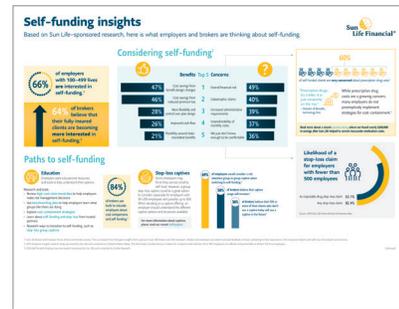
2017 Captives white paper



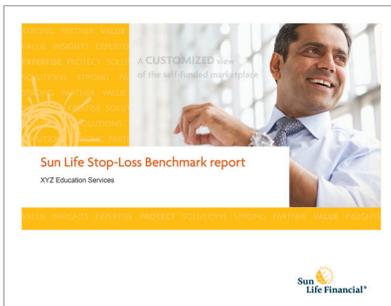
Broker education library flyer



Clinical 360 flyer



Self-funded insights graphic



Customized Stop-Loss Benchmark Report

Unbiased peer group analysis to help employers make decisions about stop-loss coverage.

For the latest information about stop-loss, please visit www.sunlife.com/stoploss or contact your Sun Life Stop-Loss Specialist.

Here for you

To learn more, contact your broker or
Sun Life Stop-Loss Specialist.



Group stop-loss insurance policies are underwritten by Sun Life Assurance Company of Canada (Wellesley Hills, MA) in all states, except New York, under Policy Form Series 07-SL REV 7-12. In New York, group stop-loss insurance policies are underwritten by Sun Life and Health Insurance Company (U.S.) (Lansing, MI) under Policy Form Series 07-NYSL REV 7-12. Product offerings may not be available in all states and may vary depending on state laws and regulations. The following services are not insurance and carry a separate charge included with the price of coverage: SunResources®, owned by Sun Life; SunExcel®, owned by Sun Life; and SunEliteSM, owned by Sun Life with services provided by third-party The Phia Group, LLC. Sun Life is not responsible or liable for the services or advice provided by any third-party vendor. Sun Life reserves the right to discontinue any service at any time. All products, brands, and names are the property of their respective owners.

© 2019 Sun Life Assurance Company of Canada, Wellesley Hills, MA 02481. All rights reserved. Sun Life Financial and the globe symbol are registered trademarks of Sun Life Assurance Company of Canada. Visit us at www.sunlife.com/us.

GSLPB-8592o

SLPC 29596 05/19 (exp. 05/24)