



Iatrogenic Infertility Due to Cancer Treatments: A Case for Fertility Preservation Coverage

"After my diagnosis I found myself in a position I never thought I would be—banking sperm. It was initially an awkward experience but looking back it was the most important thing I could have done. That decision to bank gave me the three greatest gifts in this world."

— Lance Armstrong

EXECUTIVE SUMMARY

Goal

LIVESTRONG's goal is to amend current cancer benefits to include coverage for all standard fertility preservation treatments when necessary medical treatments may cause iatrogenic infertility.

Case for Coverage

- *Iatrogenic Condition*
In order to survive their disease, cancer patients must undergo medically necessary treatments that can directly or indirectly cause iatrogenic infertility. Cancer benefits typically include coverage for the remedy of iatrogenic conditions, including procedures that are otherwise considered elective.
- *Right to Parity*
The concept of do no harm and the medical community's responsibility to mitigate iatrogenic harms is well established in medical ethics, federal laws and current insurance practices.
- *Benefit Already Exists*
Fertility preservation is already covered as a part of cancer care with the exception of two of the most successful treatment choices: sperm and embryo cryopreservation.
- *Low Usage, Low Cost, Positive Returns*
The at-risk population is small, the cost per member per month is low, and there is potential for significant positive cost offsets.
- *Avoids Risk of Adverse Selection*
Rapid initiation timelines for cancer treatments are such that there is a very low risk of patients switching policies to take advantage of this benefit.

Return on Investment

Outcome	Potential benefit
Improved patient decision making	More efficacious, less costly outcomes
Payer control over fertility preservation centers	Better outcomes, including fewer high order multiples later
Decreased distress	Reduced depression and anxiety treatment costs
Improved quality of life	Better outcomes and decreased psychosocial support costs
Positive PR & Media generated by LIVESTRONG	Positive exposure to the cancer community and general public in a relatively negative insurance climate
Good corporate citizenship	Employee loyalty

Summary

Both the emotion-laden fairness case and positive return economics provide a strong basis for coverage consideration. This easy to implement benefit modification will remedy iatrogenic infertility as well as improve outcomes, reduce distress, enable better treatment decision-making, and increase corporate goodwill.

BACKGROUND

LIVESTRONG's goal is to amend current cancer benefits to include coverage for all standard fertility preservation treatments when necessary medical treatments may cause iatrogenic infertility.

Annually, more than 130,000 patients are diagnosed with cancer during their reproductive years (under 45 years).^{1,2} Fortunately, the 5-year survival rate for these patients is 79%.³ However, in order to survive their disease, cancer patients must undergo medically necessary treatments that can directly or indirectly cause iatrogenic infertility, including surgery, radiation, chemotherapy, and targeted and hormonal therapies.⁴

Iatrogenesis refers to any adverse condition in a patient resulting from medical treatment. Infertility caused by cancer treatments is iatrogenic – an unintended consequence of treatment akin to other medical side effects of cancer treatment, such as nausea, fatigue, hair loss, and amputation.

The concept of nonmaleficence (*primum non nocere* – first, do no harm) is well established in medical ethics. This concept underpins certain acts and laws that have been passed that recognize the medical realm's responsibility for iatrogenic harms, including the Women's Health & Cancer Rights Act of 1998.⁵ The Act requires insurers to cover breast reconstruction and breast prostheses after mastectomy. Consistent with this rationale, cancer benefits typically include coverage for the remedy of other iatrogenic conditions resulting from cancer treatments, even when the same procedures are considered elective and not covered in non-iatrogenic scenarios. In addition to breast reconstruction, a few examples include coverage for lymphedema treatment, wigs, prosthetics, and antiemetics.⁶

Unmet needs about reproductive options are associated with increased distress in cancer survivors.^{7,8} Research shows that infertility affects a cancer survivor's long-term quality of life by causing unresolved grief and depression, as well as reduced life satisfaction and increased anxiety.⁹

It has also been demonstrated that patients make treatment decisions based on potential reproductive harm.¹⁰ Some evidence suggests that patients may choose a less efficacious treatment strategy in order to avoid greater toxicity and long-term complications. For example, if given a choice, young women with early-stage breast cancer may choose a less toxic regimen of chemotherapy even if it confers slightly less protection from recurrence in order to avoid iatrogenic harms, including loss of fertility.¹¹

Several fertility preservation treatments are already covered to mitigate reproductive harm for cancer patients, including radical trachelectomy, ovarian transposition, and radiation shielding. However, the two most successful, proven fertility preservation options available have been excluded from cancer coverage: sperm and embryo cryopreservation.¹²

Accordingly, LIVESTRONG is advocating for cancer coverage that includes coverage for fertility preservation to remedy iatrogenic infertility, reduce patient distress, enable better treatment decision-making, and increase corporate goodwill.

SUGGESTED BENEFIT LANGUAGE, INCLUSIONS & EXCLUSIONS

Suggested Benefit Language

Coverage for medically necessary expenses for standard fertility preservation treatments when a necessary medical treatment may directly or indirectly cause iatrogenic infertility.^A

Diagnosis Code

- v26.82 - Encounter for fertility preservation procedure

Criteria

- Patient is of reproductive age (0-45)
- Necessary medical treatments that are fertility compromising currently include:
 - » Fertility-compromising surgeries, radiation treatments and chemotherapy protocols
 - » Targeted cancer therapies that are fertility-compromising and/or do not allow the patient to achieve pregnancy during his/her reproductive years
 - » Hormone therapies that are fertility-compromising and/or do not allow the patient to achieve pregnancy during his/her reproductive years
- Standard fertility preservation treatments currently include:^B
 - » Radical trachelectomy (57531)
 - » Ovarian transposition (58825)
 - » Radiation shielding (77334)
 - » Sperm cryopreservation (See below)
 - » Embryo cryopreservation (See below)
- Fertility preservation treatment is not contraindicated

Inclusions

The following customary services are intended to be included in coverage:

Embryo Freezing

Monitoring & Laboratory Services

- Office visits (99213)
- Ultrasound (76856)
- Venipuncture (36415)
 - » Luteinizing Hormone (83002)
 - » Progesterone Level (84144)
 - » FSH Level (83001)
 - » Beta-HCG Quantitative (84702)
 - » Estradiol Level (82670)
- Nursing visit (99211)
- Cycle Management Fee (99358)

“As a doctor, my oath is to do no harm. As an oncologist, my priority is to cure cancer. As a cancer survivor, my focus is quality of life.”

– Dr. Hayes-Lattin, Testicular Cancer

^A If fertility benefits are already provided, another coverage option is to amend the definition of infertility to apply to fertility preservation for iatrogenic infertility as caused by necessary medical treatments.

^B Several fertility preservation technologies are currently considered experimental, including but not limited to oocyte cryopreservation and ovarian tissue freezing. When these technologies are no longer experimental, it is our intention that they will be included in this benefit coverage.

Medication, Retrieval & Freezing

- Ultrasonic Guidance for Aspiration of OVA (76948)
- Follicle Puncture for Oocyte Retrieval (58970)
- Culture of Oocytes (89250, 89251)
- Oocyte identification from Follicular Fluid (89254)
- Insemination of Oocytes (89268)
- Extended Culture of Oocytes/Embryo(s), when necessary (89272)
- Anesthesia (00840)
- Medications (99070)
- Educational Instruction (99078)
- Extended culture of embryos, when necessary (89272)
- Intracytoplasmic sperm injection (ICSI), when necessary (89280, 89281)
- Embryo cryopreservation (freezing services, not storage) (89258)

Sperm Cryopreservation

- Semen analysis (89320)
- Cryopreservation of semen (89259)
- Sperm delivery/handling (99199)

Exclusions

This benefit is not intended to cover the following; however, other existing benefits may already include coverage for these services:

- Storage (per year) (89342, 89343)
- Assisted reproductive technologies for future conception (IUI: 58321, 58322, 58323 + all IVF CPT Codes)
 - » Thawing of cryopreserved embryos (89352)
 - » Thawing of cryopreserved sperm (89354)
 - » Preparation of embryo for transfer (89255)
 - » Embryo transfer (58974, 58976)
- Pre-implantation genetic diagnosis (PGD) and other genetic testing (89290, 89291)
- Experimental/investigational fertility preservation treatments (89240, 0058T, 0059T)
- Assisted embryo hatching procedures (89253)
- Donor egg, sperm or embryos (S4023, S4025, S4026)
- Gestational Carrier (surrogacy) (v26.89 + IVF + Prenatal CPT Codes)
- Prenatal care (9400, 59510, 59610, 59618, 59425, 59426)

Note: The lists of CPT Codes above may not be all-inclusive.

"I was diagnosed with cancer when I was 24. I was told my treatments might make me sterile. Even though I was single, I banked my sperm. I am now a proud father. It should be that easy for everyone."

– Michael, Hodgkin's Lymphoma

COST ANALYSIS

Example Cost Analysis Assumptions	
Percent of Cancer Patients Age 0-45 ¹³	9.5%
Percent Women ¹⁴	49%
Percent Men ¹⁵	51%
Percent of These Patients at Risk for Infertility from Cancer Treatments ¹⁶	60%
Percent of at Risk WOMEN that Take Action to Preserve their Fertility ¹⁷	24%
Percent of at Risk MEN that Take Action to Preserve their Fertility ¹⁸	24%
Average Cost of Sperm Banking ¹⁹	\$576
Average Cost of Embryo Freezing Treatments ²⁰	\$9,250
Average Cost of Embryo Freezing Medications ²¹	\$4,500
Average Number of Sperm Bank Deposits	2
Average Number of Embryo Freezing Cycles	1
Cost Share for Medical Treatments	20%
Cost Share for Drugs (Co-Pay)	\$200

Example Cost Analysis	
Sample Insurance Company Members	1,000,000
# Diagnosed with Cancer 0-45	458
# At Risk for Infertility	275
# Undergo Fertility Preservation	66
• # Men	34
• # Women	32
Cost for Sperm Banking	\$30,983
Cost of Embryo Freezing	\$377,913
Total Cost Per Year	\$408,895
Cost Per Member Per Month (PMPM)	\$.03

BENEFIT IMPACT

Low usage	As few as 0.03% of the population (133,000) is diagnosed with cancer during their reproductive years and is subsequently at risk for iatrogenic infertility. ²²
Low cost	<p>The cost per member per month of adding coverage of sperm and embryo cryopreservation costs is low.²³</p> <p>The cost of sperm and embryo cryopreservation for cancer patients would represent very small percent of the total direct medical costs for cancer in the US per year – estimated at 0.12%.²⁴</p> <p>The costs of sperm and embryo cryopreservation are on par with the costs of other already covered iatrogenic conditions caused by cancer.²⁵</p>
Avoids adverse selection	The average cancer patient has 4-6 weeks between diagnosis and the initiation of treatment when they must undergo fertility preservation making it very difficult to switch insurance policies to take advantage of this benefit.
Reduces distress	<p>Unmet needs about reproductive options are associated with increased distress in cancer survivors.^{26, 27}</p> <p>Survivors' long-term quality of life is affected by unresolved grief and depression, as well as reduced life satisfaction and increased anxiety.²⁸</p>
Improves decision-making	<p>Patients make treatment decisions based on potential reproductive harm.²⁹</p> <p>Some evidence suggests that patients may choose a less efficacious treatment strategy in order to avoid greater toxicity and long-term complications, including fertility.³⁰</p>
Family-Friendly	Adding coverage for fertility preservation for iatrogenic infertility as caused by cancer treatments adds value to your family-friendly benefits portfolio.
Positive PR & Media	LIVESTRONG will positively recognize the policies of companies that improve fertility preservation benefits for young adult cancer patients to millions.
Good corporate citizenship	<p>Businesses that incorporate corporate social responsibility directly into their business strategies and proactively promote the public interest by voluntarily eliminating practices that harm the public sphere see increased customer and employee loyalty.³¹</p> <p>Increasingly, corporations are ethically, legally and economically motivated to become more socially responsible because their most important stakeholders expect them to understand and address issues that are relevant to them.³²</p>

IATROGENIC INFERTILITY vs. TRADITIONAL INFERTILITY COVERAGE

Coverage for iatrogenic infertility for cancer patients is very different than traditional infertility coverage and, accordingly, should be evaluated as a part of cancer-care, not part of traditional infertility coverage.

Iatrogenic condition	For cancer patients, infertility is an iatrogenic condition that results from medically necessary cancer treatments. ³³
Smaller patient population	Annually, there are 133,000 at risk cancer patients compared to 2,000,000 traditional infertility patients. ³⁵
Limited number of cycles	Unlike traditional fertility patients who can continue to receive infertility treatments until they conceive, cancer patients often only have time to undergo one cycle before they start cancer treatments. ³⁶
Lower cost	<p>The cost per member per month of coverage for iatrogenic infertility is in the single digits whereas the cost per member per month for traditional infertility coverage is \$1.71.³⁷</p> <p>Covering sperm and embryo cryopreservation for cancer patients is 94% less expensive than covering assisted reproductive technologies for traditional infertility.³⁸</p>
Avoids adverse selection	As noted above, it would be very hard for cancer patients to switch insurance policies to take advantage of this benefit.

"I had a plan for where I wanted to be in life, but spending the first year of my marriage bald and infertile was not something that I'd considered! When my physician spoke to me about treatment I got a lump in my throat and my eyes welled with tears as I realized that the chemo was about to destroy my ability to have children."

– Debbie, Breast Cancer

REFERENCES

- ¹ National Cancer Institute: <http://seer.cancer.gov/statfacts/html/all.html>
- ² ACS Cancer Facts & Figures: http://www.cancer.org/docroot/stt/stt_0.asp
- ³ National Cancer Institute: http://seer.cancer.gov/csr/1975_2007/results_merged/topic_survival.pdf
- ⁴ Lee SJ, Schover LR, Partridge AH, et al: American Society of Clinical Oncology recommendations on fertility preservation in cancer patients. *J Clin Oncol* 24:2917-2931, 2006
- ⁵ American Cancer Society: http://www.cancer.org/docroot/mit/content/mit_3_2x.asp
- ⁶ Campo-Engelstein L, Consistency in Insurance Coverage for Iatrogenic Conditions Resulting From Cancer Treatment Including Fertility Preservation, *J Clin Oncol*. 2010 Mar 10;28(8):1284-6
- ⁷ Carter, J et al: A cross-sectional study of the psychosexual impact of cancer-related infertility in women: third-party reproductive assistance. *J Cancer Surviv*. 2010 Apr 7
- ⁸ Lee SJ, Schover LR, Partridge AH, et al: American Society of Clinical Oncology recommendations on fertility preservation in cancer patients. *J Clin Oncol* 24:2917-2931, 2006
- ⁹ Ibid.
- ¹⁰ Ruddy KJ, Partridge AH, Breast cancer in young women: clinical decision-making in the face of uncertainty, *Oncology*, 2009 May;23(6):474, 477
- ¹¹ Partridge AH, Gelber S, Peppercorn J, et al: Web-based survey of fertility issues in young women with breast cancer. *J Clin Oncol* 22:4174-4183, 2004; See also discussion of parallel rationale as a factor in the passage of the Women's Health and Cancer Rights Act of 1998. "The availability of reconstructive surgery is important not only for those women who believe it is necessary to return their lives to normal following cancer surgery, but because studies show that the fear of losing a breast is a leading reason why women do not participate in early breast cancer detection programs. If women understand that breast reconstruction is widely available, more might participate in detection programs." Congressional Record, January 29, 1997, comments by Sen. Olympia Snowe).
- ¹² Campo-Engelstein L, Consistency in Insurance Coverage for Iatrogenic Conditions Resulting From Cancer Treatment Including Fertility Preservation, *J Clin Oncol*. 2010 Mar 10;28(8):1284-6
- ¹³ See supra, footnote 1; number of patients diagnosed under 45, calculated as a percentage of the US population, figures based on 2010 US Census.
- ¹⁴ See supra footnote 2
- ¹⁵ Ibid.
- ¹⁶ See supra footnote 4
- ¹⁷ Fertil Steril. 2010 Jun;94(1):149-55. Epub 2009 May 5. Fertility preservation for female cancer patients: early clinical experience. Klock SC, Zhang JX, Kazer RR.
- ¹⁸ Ibid.
- ¹⁹ LIVESTRONG database
- ²⁰ Ibid.
- ²¹ EMD Serono
- ²² See supra, footnote 1; number of patients diagnosed under 45, calculated as a percentage of the US population, figures based on 2010 US Census.
- ²³ LIVESTRONG document Cost of Fertility Preservation.
- ²⁴ Cancer care accounted for an estimated \$104.1 billion in medical care expenditures in the United States in 2006 - http://progressreport.cancer.gov/doc_detail.asp?pid=1&did=2007&chid=75&coid=726&mid

²⁵

Procedure	Cost	Source
Laparoscopic ovarian transposition	\$4,010	Memorial Sloan-Kettering Cancer Center
Radical Trachelectomy	\$15,000-\$17,000	Memorial Sloan-Kettering Cancer Center
Breast reconstruction		Kaplan JL, Allen RJ., Cost-based comparison between perforator flaps and TRAM flaps for breast reconstruction. <i>Plast Reconstr Surg</i> . 2000 Mar;105(3):943-8.
- Perforator Flap	\$9,625	http://www.plasticsurgeryportal.com/breast-reconstruction/2002111209240586941583
- TRAM Flap	\$18,070	
- Breast implants	\$7,000	
Embryo Cryopreservation	\$9,250	LIVESTRONG database
Embryo Cryopreservation Medications	\$4,500	Pharmaceutical company
Sperm Cryopreservation	\$526	LIVESTRONG database

²⁶ Carter, J et al: A cross-sectional study of the psychosexual impact of cancer-related infertility in women: third-party reproductive assistance. *J Cancer Surviv*. 2010 Apr 7

²⁷ Lee SJ, Schover LR, Partridge AH, et al: American Society of Clinical Oncology recommendations on fertility preservation in cancer patients. *J Clin Oncol* 24:2917-2931, 2006

²⁸ Ibid.

²⁹ Ruddy KJ, Partridge AH, Breast cancer in young women: clinical decision-making in the face of uncertainty, *Oncology*, 2009 May;23(6):474, 477

³⁰ Partridge AH, Gelber S, Peppercorn J, et al: Web-based survey of fertility issues in young women with breast cancer. *J Clin Oncol* 22:4174-4183, 2004; See also discussion of parallel rationale as a factor in the passage of the Women's Health and Cancer Rights Act of 1998. "The availability of reconstructive surgery is important not only for those women who believe it is necessary to return their lives to normal following cancer surgery, but because studies show that the fear of losing a breast is a leading reason why women do not participate in early breast cancer detection programs. If women understand that breast reconstruction is widely available, more might participate in detection programs." Congressional Record, January 29, 1997, comments by Sen. Olympia Snowe).

³¹ http://en.wikipedia.org/wiki/Corporate_social_responsibility

³² Ibid.

³³ Campo-Engelstein L, Consistency in Insurance Coverage for Iatrogenic Conditions Resulting From Cancer Treatment Including Fertility Preservation, *J Clin Oncol*. 2010 Mar 10;28(8):1284-6

³⁴ Supra, footnote 1.

³⁵ RESOLVE: [\http://www.resolve.org/site/PageServer?pagenam=fmed_mcff_ff\](http://www.resolve.org/site/PageServer?pagenam=fmed_mcff_ff)

³⁶ Campo-Engelstein L, Consistency in Insurance Coverage for Iatrogenic Conditions Resulting From Cancer Treatment Including Fertility Preservation, *J Clin Oncol*. 2010 Mar 10;28(8):1284-6

³⁷ Griffin M, Panak WF. The economic cost of infertility-related services: an examination of the Massachusetts insurance mandate. *Fertil Steril* 1998;70:22-9.

³⁸ Ibid.