PARMA CITY SCHOOLS DISTRICT

MINUTES

INSURANCE COMMITTEE MEETING

May 14, 2024

Meeting called to order at 1:30 p.m.

Financials

- Sean discussed the Financials for the Insurance Fund. The fund balance as of 4/30/2024 was $5,385,021.92. Expenditure exceeded revenues for the month of April.

Wellness

- There was no wellness update.

Oswald

- Oswald provided their monthly financial update. The medical insurance premium increase will be 5.48% for fiscal year 2025.

Galleri

- Emily from Galleri provided details on how the testing works. So far, seven employees have signed up for the test.

Meeting was adjourned at 2:00 p.m.

Next meeting: No meeting in June. Our next meeting will be in September.

Fiscal Year	2024	2023	2022
FY Beg. Balance (cash)	**$ 6,985,590.17**	**$ 6,795,523.85**	**$ 6,670,919.06**
Premiums			
Employees - Med/Rx	$ 2,546,549.43	$ 3,142,631.17	$ 3,169,690.73
Vision - Emp	$ 923.53	$ 130,611.53	$ 1,229.04
Board of Education - Med/Rx	$ 17,057,968.04	$ 21,320,951.37	$ 20,561,037.63
Vision - BoE	$ 101,877.21	$ 931.68	$ 135,974.15
Misc	$ 41,107.73	$ 140,010.50	$ 9,703.71
Total Revenue	***$ 19,748,425.94***	*$ 24,735,136.25*	*$ 23,877,635.26*
Total Expense	***$ 21,348,994.19***	*$ 24,545,069.93*	*$ 23,753,030.47*
Reserve Gain/(Loss)	***$ (1,600,568.25)***	***$ 190,066.32***	***$ 124,604.79***
Claims			
Medical	$ 13,226,385.20	$ 16,726,665.33	$ 16,659,826.69
Prescription	$ 5,159,571.02	$ 4,864,063.60	$ 4,394,392.30
Vision	$ 86,615.40	$ 82,607.75	$ 100,206.56
Fixed Costs & Other			
Administration Fee	$ 547,785.92	$ 784,277.35	$ 635,960.30
Stop Loss Premiums	$ 2,061,952.23	$ 1,862,905.66	$ 1,813,794.64
Consultant/Legal Fees	$ 217,297.33	$ 199,687.79	$ 121,892.17
Subrogation	$ 6,018.22	$ 2,745.24	$ 5,001.98
Health Fair/Wellness	$ 9,707.41	$ 12,034.21	$ 9,391.59
ACA Fees	$ -	$ -	$ -
Misc	$ 33,661.46	$ 10,083.00	$ 12,564.24
FY Ending Balance (cash)	**$ 5,385,021.92**	**$ 6,985,590.17**	**$ 6,795,523.85**

FY 2024 Insurance Fund by Month

Total FYTD			July	August	September	October	November	December	January	February	March	April
	Premiums											
$ 2,546,549.43	Employees	(3)	$ 120,560.46	$ 220,801.46	$ 253,998.70	$ 251,178.39	$ 251,733.36	$ 252,704.98	$ 397,236.20	$ 265,209.75	$ 267,491.33	$ 265,634.80
$ 923.53	Vision - Emp	(5)	$ 43.27	$ 71.27	$ 113.42	$ 82.08	$ 199.78	$ 79.76	$ 83.58	$ 81.80	$ 86.77	$ 81.80
$ 17,057,968.04	Board of Education	(2)	$ 1,569,487.28	$ 1,565,495.84	$ 1,393,079.19	$ 1,779,850.59	$ 1,786,478.03	$ 1,797,713.08	$ 1,791,944.19	$ 1,795,508.97	$ 1,794,766.67	$ 1,783,644.20
$ 101,877.21	Vision - BOE	(4)	$ 9,315.53	$ 9,343.94	$ 8,304.30	$ 10,552.52	$ 10,610.00	$ 10,687.26	$ 10,725.45	$ 10,776.33	$ 10,817.67	$ 10,744.21
$ 41,107.73	Misc	(1)	$ 27,500.00	$ -		$ 3,917.69	$ 3,380.23				$ 1,309.81	$ 5,000.00
$ 19,748,425.94	***Total Revenue***		*$ 1,726,906.54*	*$ 1,795,712.51*	*$ 1,655,495.61*	*$ 2,045,581.27*	*$ 2,052,401.40*	*$ 2,061,185.08*	*$ 2,199,989.42*	*$ 2,071,576.85*	*$ 2,074,472.25*	*$ 2,065,105.01*
$ 21,348,994.19	***Total Expense***		*$ 2,871,508.45*	*$ 1,722,770.95*	*$ 1,767,708.94*	*$ 1,857,717.15*	*$ 1,943,792.49*	*$ 2,133,002.68*	*$ 2,554,980.37*	*$ 1,716,536.11*	*$ 2,048,753.35*	*$ 2,732,223.70*
$ (1,600,568.25)	***Reserve Gain/(Loss)***		*$ (1,144,601.91)*	*$ 72,941.56*	*$ (112,213.33)*	*$ 187,864.12*	*$ 108,608.91*	*$ (71,817.60)*	*$ (354,990.95)*	*$ 355,040.74*	*$ 25,718.90*	*$ (667,118.69)*
	Claims											
$ 13,226,385.20	Medical	(1)	$ 1,647,810.33	$ 998,270.12	$ 1,497,817.15	$ 1,022,047.96	$ 1,155,474.23	$ 1,287,816.62	$ 1,494,808.93	$ 1,310,980.42	$ 1,357,817.18	$ 1,453,542.26
$ 5,159,571.02	Prescription	(2)	$ 679,501.89	$ 460,869.05	$ 1,828.70	$ 553,849.02	$ 500,151.51	$ 586,130.66	$ 784,810.01	$ 166,441.35	$ 667,907.75	$ 758,081.08
$ 86,615.40	Vision	(5)	$ 7,856.01	$ 8,508.26	$ 8,536.78	$ 7,431.80	$ 11,389.38	$ 6,791.03	$ 4,991.62	$ 8,737.82	$ 4,220.42	$ 18,152.28
	Fixed Costs & Other											
$ 547,785.92	Administration Fee	(4)	$ 101,228.17	$ 51,310.04	$ 52,011.73	$ 53,056.44	$ 52,901.31	$ 52,582.94	$ 53,027.88	$ 24,112.92	$ 3,904.60	$ 103,649.89
$ 2,061,952.23	Stop Loss Premiums	(3)	$ 374,946.17	$ 186,461.16	$ 184,988.14	$ 188,418.48	$ 188,034.34	$ 188,666.53	$ 188,199.13	$ 186,559.60	$ -	$ 375,678.68
$ 217,297.33	Consultant/Legal Fees	(6)	$ 31,360.12	$ 12,915.66	$ 22,193.66	$ 31,726.46	$ 35,571.63	$ 8,724.80	$ 28,158.00	$ 18,461.00	$ 9,725.00	$ 18,461.00
$ 6,018.22	Subrogation	(7)	$ 319.30	$ 296.66	$ 332.78	$ 1,186.99	$ 270.09	$ 1,255.10	$ 984.80	$ 328.00	$ 1,044.50	$ -
$ 9,707.41	Health Fair/Wellness	(9)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 915.00	$ 4,133.90	$ 4,658.51
$ -	ACA Fees	(8)	$ -	$ -	$ -	$ -	$ -	$ -	$ -			
$ 33,661.46	Misc	(10)	$ 28,486.46	$ 4,140.00	$ -	$ -	$ -	$ 1,035.00	$ -			

Health Care Committee Meeting

May 14, 2024

Tracie Collins
Jean Linkous

We See Risk So You See Opportunity



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Oswald Monthly Report

Claim Experience - Prior Year	Jul 22	Aug 22	Sep 22	Oct 22	Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	Apr 23	May 23	Jun 23	Total	Average	PEPY
Medical Claims	$1,304,600	$1,912,085	$1,553,556	$1,445,212	$1,297,010	$1,393,691	$1,562,052	$1,159,747	$1,607,331	$1,756,137	$1,514,431	$1,267,860	$17,773,722	$1,481,144	$14,852
Prescription Claims	$400,384	$509,000	$461,854	$459,359	$514,833	$407,282	$506,055	$450,417	$477,049	$454,983	$564,792	$473,936	$5,659,944	$471,662	$4,729
Rx Rebates	($96,971)	($96,971)	($96,971)	($98,468)	($98,468)	($98,468)	($119,998)	($119,998)	($119,998)	($160,625)	($160,625)	($160,625)	($1,428,187)	($119,016)	($1,193)
Total Claims	**$1,608,012**	**$2,324,124**	**$1,918,439**	**$1,786,103**	**$1,713,375**	**$1,702,506**	**$1,948,109**	**$1,490,166**	**$1,964,381**	**$2,050,495**	**$1,918,598**	**$1,581,172**	$22,005,479	$1,833,790	**$18,388**
Fees/Premium	$221,497	$219,180	$214,945	$217,217	$217,926	$218,076	$218,479	$218,328	$217,619	$218,175	$217,721	$217,570	$2,616,733	$218,061	$2,187
Total Cost	$1,829,509	$2,543,304	$2,133,383	$2,003,320	$1,931,301	$1,920,582	$2,166,588	$1,708,494	$2,182,001	$2,268,670	$2,136,319	$1,798,742	$24,622,212	$2,051,851	$20,574
Reimbursed Claims													($1,262,196)		($1,055)
Grand Total													$23,360,076	$1,946,673	$19,520

Subscribers Medical/Rx	1,207	1,199	1,178	1,193	1,200	1,200	1,201	1,201	1,194	1,198	1,195	1,195	14,361	1,197	
Medical/Rx Claim PEPM	$1,332.24	$1,938.52	$1,628.56	$1,497.15	$1,427.81	$1,418.75	$1,622.07	$1,240.77	$1,645.21	$1,711.60	$1,605.52	$1,323.16		$1,535	$18,388

Claims Experience - Current Year	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24	Total	Average	PEPY
Medical Claims	$1,392,477	$1,724,247	$1,073,455	$1,071,518	$1,326,658	$1,232,913	$1,467,222	$1,363,890	$1,541,174				$12,193,633	$1,354,848	$13,620
Prescription Claims	$551,915	$611,719	$479,289	$690,202	$476,617	$691,173	$662,565	$541,675	$587,341				$5,292,497	$588,055	$5,912
Rx Rebates	($122,890)	($122,890)	($122,890)										($368,671)	($122,890)	($412)
Total Claims	**$1,821,501**	**$2,213,075**	**$1,429,854**	**$1,761,720**	**$1,803,256**	**$1,924,086**	**$2,129,787**	**$1,905,565**	**$2,128,615**				$17,117,460	$1,820,013	**$19,120**
Fees/Premium	$236,245	$232,021	$235,806	$237,507	$238,494	$238,220	$235,751	$236,410	$237,562				$2,128,017	$236,446	$2,377
Total Cost	$2,057,747	$2,445,096	$1,665,660	$1,999,227	$2,041,750	$2,162,306	$2,365,539	$2,141,975	$2,366,177				$19,245,476	$2,138,386	$21,497
Reimbursed Claims													($245,798)		($272)
Grand Total													$19,001,678	$2,111,298	$21,225

Subscribers Medical/Rx	1,193	1,168	1,189	1,197	1,206	1,205	1,193	1,193	1,199				10,743	1,194	
Medical/Rx Claim PEPM	$1,526.82	$2,094.76	$1,202.57	$1,471.78	$1,495.24	$1,598.75	$1,785.24	$1,597.29	$1,775.53					$1,594	$19,120



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Oswald Monthly Report (cont.)

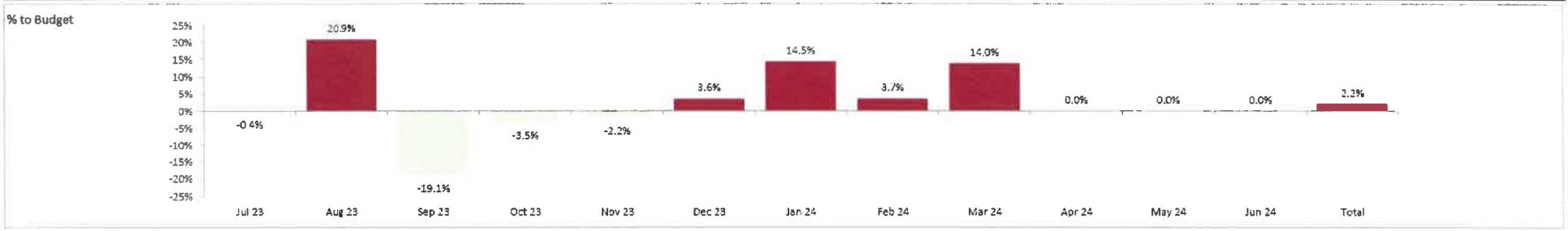


Large Claims: July 2023 - June 2024	Claims	Estimated Reimbursement
	$398,398	($198,398)
	$242,270	($42,270)
	$203,130	($3,130)
	$199,324	
	$198,263	
	$180,291	
	$145,615	
	$145,408	
	$136,112	
	$130,954	
	$1,979,765	($243,796)

Plan Information	
Insurer/Medical	MMO
Rx	ESI
Contract Type	Self-Insured
Specific Stop-Loss Coverage	Medical/Rx
Specific Stop-Loss Deductible	$200,000
Aggregate Stop-Loss Coverage	Medical/Rx
Aggregate Stop-Loss Corridor	115%

Due to reporting limitations, reimbursements are shown on medical claims only.
The stop loss contract covers both medical and Rx claims so actual reimbursements may differ.

Year to Date Actual vs Budgeted Plan Cost	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24	Total	Average	PEPY
Budget Plan Cost	$2,065,549	$2,022,264	$2,058,623	$2,072,474	$2,088,057	$2,086,325	$2,065,549	$2,065,549	$2,075,937				**$18,600,327**	$2,066,703	$20,777
Actual Plan Cost	$2,057,747	$2,445,096	$1,665,660	$1,999,227	$2,041,750	$2,162,306	$2,365,539	$2,141,975	$2,366,177				**$19,001,678**	$2,138,386	$21,225
% Actual to Budget	99.6%	120.9%	80.9%	96.5%	97.8%	103.6%	114.5%	103.7%	114.0%				**102.2%**		



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July 2024 Projection

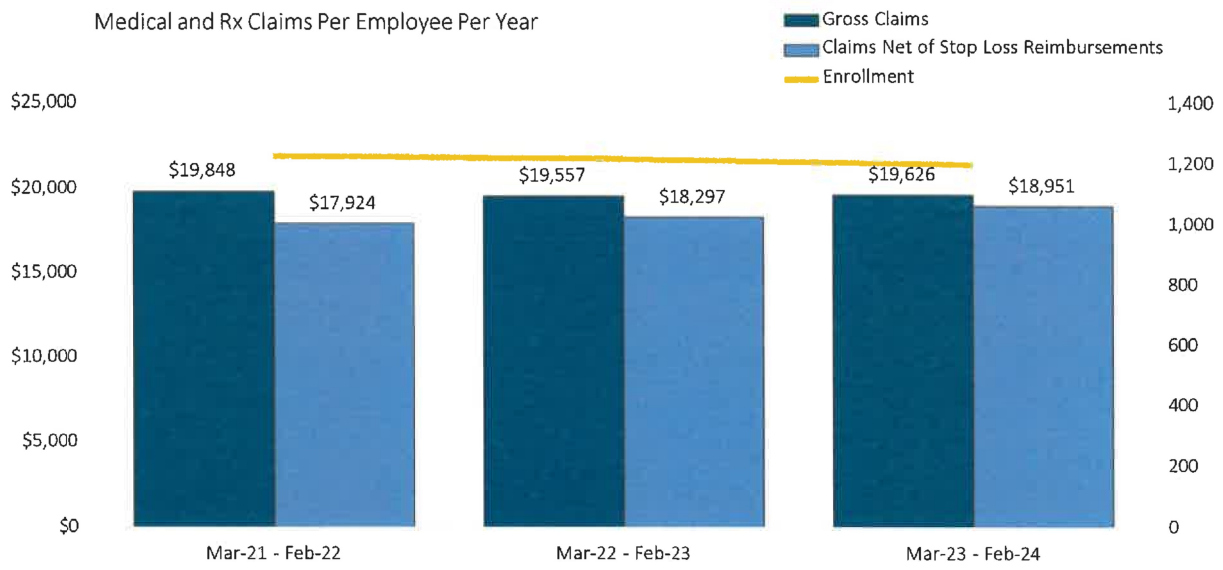
Self-Funded Projection

Parma City School District

July 2024

Historical Experience

Medical/Rx



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Claims Projection

Medical/Rx

	Medical		Prescription Drug		Combined	
Experience Period	March-23 Through February-24	March-22 Through February-23	March-23 Through February-24	March-22 Through February-23	March-23 Through February-24	March-22 Through February-23
Total Paid Claims	$16,798,119	$18,266,772	$6,658,124	$5,456,128	$23,456,243	$23,722,900
Less Total Large Claims	$2,606,330	$3,728,749			$2,606,330	$3,728,749
Net Claims	**$14,191,789**	**$14,538,023**	**$6,658,124**	**$5,456,128**	**$20,849,913**	**$19,994,151**
Annual Trend[1]	7.40%	7.40%	9.80%	9.80%		
Trend Adjustment	1.100	1.181	1.133	1.244		
Demographic Adjustment	0.990	0.980	0.990	0.980		
Plan Change Adjustment	1.000	1.000	1.000	1.000		
Projected Claims (Excludes Large Claims)	$15,452,950	$16,829,637	$7,466,611	$6,650,426	$22,919,560	$23,480,063
Large Claims Under the Specific Deductible	$1,800,000	$2,200,000			$1,800,000	$2,200,000
Total Projected Claims	**$17,252,950**	**$19,029,637**	**$7,466,611**	**$6,650,426**	**$24,719,560**	**$25,680,063**
Average Enrollment[2]	**1,195**	**1,213**	**1,194**	**1,208**		
Projected Claims PEPM	**$1,202.97**	**$1,307.34**	**$521.19**	**$458.81**	**$1,724.16**	**$1,766.15**
Experience Period Weighting	80.00%	20.00%	80.00%	20.00%	80.00%	20.00%
Weighted Projected Claims						
Average PEPM	$1,223.84		$508.72		$1,732.56	
Less Expected Rebates	$0.00		$99.43		$99.43	
Average PEPM	**$1,223.84**		**$409.29**		**$1,633.13**	
Final Projected Claims PEPM					$1,633.13	

[1]Trend from 2023 Segal Trend Survey

[2]Medical enrollment lagged two months

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Self-Funded Projection

Parma City School District

July 2024

Claims Cost and Fixed Fees Summary

Medical/Rx

PEPM Cost Summary	Current	Projected Change	Estimated Projected
Projected Claims PEPM	$1,552.58	5.2%	$1,633.13
Administrative Fees PEPM	$40.32	0.0%	$40.32
Chronic Condition Management Fee	$2.50	0.0%	$2.50
Specific Stop Loss Fee PEPM	$148.36	10.0%	$163.20
Aggregate Stop Loss Fee PEPM	$8.51	6.6%	$9.07
Total Cost PEPM	$1,752.28	5.48%	$1,848.22

Projected Annual Cost	Current		Estimated Projected
Enrollment	1,193		1,193
Projected Claims	$22,226,788	5.2%	$23,379,878
Total Fixed Fees	$2,858,810	7.7%	$3,079,232
Total Budgeted/Projected Annual Cost	$25,085,598	5.48%	$26,459,110

Self-Funded Projection

Parma City School District

July 2024

Premium Equivalent Rates

Medical/Rx

Plan & Tier	Current Enrollment	Current Medical and Drug Rates	Projected Medical and Drug Rates	Projected Rate Change	Projected COBRA Rates
PEA SMP PPO					
Employee Only	207	$916.20	$966.36	5.48%	$985.69
Employee + Family	420	$2,445.11	$2,578.99	5.48%	$2,630.57
OAPSE SMP PPO					
Employee Only	259	$974.16	$1,027.50	5.48%	$1,048.05
Employee + Family	157	$2,600.89	$2,743.30	5.48%	$2,798.16
SMP500					
Employee Only	75	$844.83	$891.09	5.48%	$908.91
Employee + Family	62	$2,255.25	$2,378.73	5.48%	$2,426.31
Bronze					
Employee Only	11	$613.96	$647.58	5.48%	$660.53
Employee + Family	2	$1,639.19	$1,728.94	5.48%	$1,763.52
Total Annual Cost	1,193	$25,085,598	$26,459,110	5.48%	

Exhibit includes ASO fees and stop loss premium but does not include PCORI fees.

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Galleri | PCSD Parma City School District

Galleri Multi-Cancer Early Detection (MCED) Test

Parma City School District

Why Multi-Cancer Early Detection?

Cancer is a leading cause of death in the US[1]

1 in 2 men will be diagnosed with cancer in their lifetime[2]

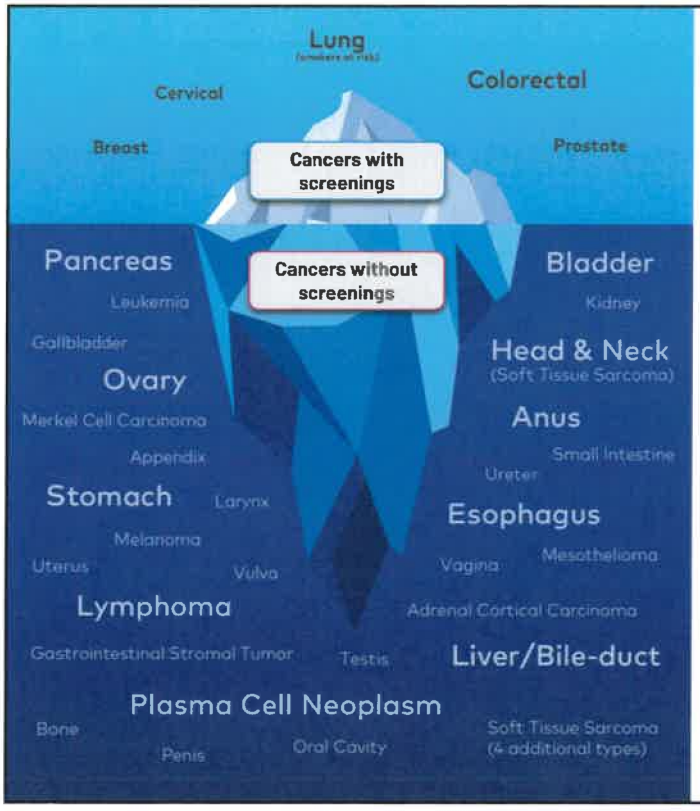
1 in 3 women will be diagnosed with cancer in their lifetime[2]

1 in 5 people will die from cancer[2]

Galleri

1. Leading Causes of Death https://www.cdc.gov/nchs/fastats/leading-causes-of-death.html
2. https://www.cancer.org/cancer/cancer-basics/lifetime-probability-of-developing-or-dying-from-cancer.html

US-GA-2300014-1



Employees face a health challenge: There are no recommended screenings for ~70% of cancers

The Galleri® multi-cancer early detection test

Now you can screen for a signal shared by 50+ cancers, with a simple blood draw.[1]

The Galleri test is also the #1 employee-ranked health benefit.[2*]

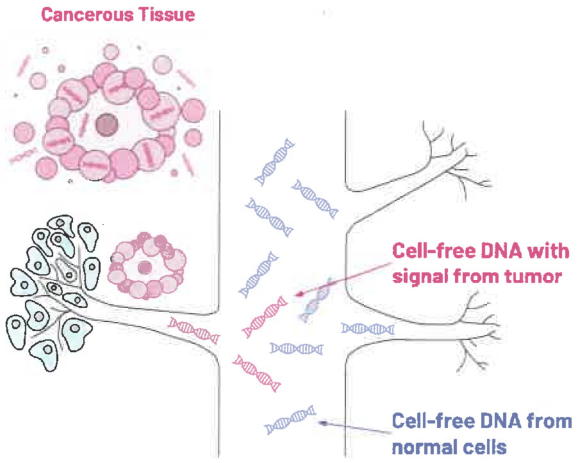
Recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older

The Galleri test does not detect a signal for all cancers and not all cancers can be detected in the blood. False positive and false negative results do occur. The Galleri test looks for a signal associated with active cancer and does not predict future genetic risk for cancer. Galleri should be used in addition to healthcare provider recommended screening tests.

*Market research included 1,000 respondents who were full-time employees working at companies with at least 3000 employees; 15% of sample aged 65+, 70% of sample aged 50-64; 15% aged under 50 with cancer risk factors. Respondents were a representative mix across gender, region, race, ethnicity.



Using machine learning and AI, Galleri can detect a cancer signal in the blood and predict the signal origin (tissue/organ)



The Galleri test does not detect a signal for all cancers and not all cancers can be detected in the blood. False positive and false negative results do occur.

All cells - healthy and cancerous - release DNA into the bloodstream, but DNA from cancer cells is different from healthy cells' DNA.

Using next-generation DNA sequencing, the Galleri test is able to identify the specific methylation pattern - a natural process used to regulate gene expression - that indicate the presence of a cancer signal.

Then, using artificial intelligence and machine learning algorithms, the Galleri test predicts the tissue or organ associated with the cancer signal.

Who is eligible?

Eligibility: PCSD employees, on PCSD health plan, who meet age criteria:



Individuals age

50 & above

This option is based on age groups that were included in clinical trials studying the safety and effectiveness of Galleri.



Individuals age

40–49

with certain risk factors

This option includes the 50+ age group, plus adults ages [40-49, your choice] with certain risk factors, based on scientific data supporting elevated risk for cancer in this age group; Galleri has not been studied in individuals under 50.

- **AT LEAST ONE of the following:**
  - Cancer survivor who was diagnosed at least 5 years ago, *excluding basal and squamous cell carcinoma of the skin*
  - Currently smokes or quit smoking less than 10 years ago

Risk factors that have an elevated risk for some cancer types but need additional evidence to quantify the risk:

- Cirrhosis or chronic Hepatitis B or C Infection
- Infection with certain strains of HPV (e.g. HPV 16 or 18)
- Known hereditary cancer syndrome:
  Confirmation and documentation of a gene mutation associated with increased cancer risk (e.g., Li-Fraumeni syndrome, Hereditary Breast and Ovarian Cancer syndrome [BRCA1/2], Lynch syndrome, CHEK2)

OR

- **AT LEAST TWO of the following:**
  - First degree relative with cancer, *excluding basal and squamous cell carcinoma of the skin*
  - History of HIV infection
  - Current use of immunosuppressive therapies after organ transplantation

BMI:

- Female ≥ 30 kg/m^2
- Male ≥ 35 kg/m^2

Galleri should be used in addition to healthcare provider recommended screening tests, such as mammography, colonoscopy, lung cancer screening (for those at risk), PSA, or cervical cancer screening.

Galleri testing process

Testing process

Request the Galleri test 1



Complete the online test request form and a provider from GRAIL's partner telemedicine group will evaluate your eligibility

**takes approximately 10 minutes*

Print your TRF and complete your blood draw 2



If your request is approved by the telemedicine provider, you will receive an email to print your test requisition form (TRF) and schedule your blood draw

Receive your test result and next steps 3



Approximately 2 weeks after your blood draw, the telemedicine provider will share your results

Visit www.galleri.com/pcsd for more information
Click "Request the Galleri test" to start the Galleri test request

Request the Galleri test

1. **Learn** about the Galleri test at www.galleri.com/pcsd
2. Click **"Request the Galleri test"** button to access the patient portal
3. **Get started by** entering basic information and your Insurance information.
4. **Submit** your test request and medical information, including your primary healthcare provider's information
5. The telemedicine provider will review your request and evaluate your clinical eligibility

The Cost of the Galleri test for eligible PCSD employees is ***$424.50***



Complete your blood draw

If the telemedicine provider approves your test request, you will receive:

1. Email confirmation with your test order document from the provider ("Test Requisition Form").
2. Galleri collection kit (shipped from GRAIL).

Schedule and complete your blood draw **as soon as possible**

You'll need your printed Test Requisition Form and your **unopened** collection kit for your blood draw appointment.



Receive your results and next steps

About two weeks after your blood draw, the telemedicine provider will contact you when your results are ready.

There are two possible test results:

Cancer Signal NOT Detected

This means that no cancer signal was found in your blood drawn. This does not rule out cancer. The Galleri test does not detect all cancers.

Continue with routine cancer screening tests your healthcare provider recommends.

Cancer Signal Detected

This means a cancer signal was detected in your blood drawn. This result is not a cancer diagnosis. Your healthcare provider will discuss next steps to confirm if cancer is present.

~99% Of cases result in a cancer signal not detected

The test does not measure your genetic risk of developing cancer in the future.
It's important to continue with any additional screenings your healthcare provider recommends.

Galleri

Your privacy matters

Your test result and medical information are **confidential** and access is limited to individuals who need the information for a specific purpose, such as

- The ordering telemedicine provider
- Your primary healthcare provider, if you supply their contact information

Your individual results will not be shared with your employer.

Your employer only receives **de-identified and aggregated information across all employees.**



Request the Galleri test at galleri.com/pcsd



Have Questions? Need Support?

GRAIL Customer Support

customerservice@grailbio.com

833-694-2553

Emily Yepes, Client Success Manager

eyepes@grailbio.com

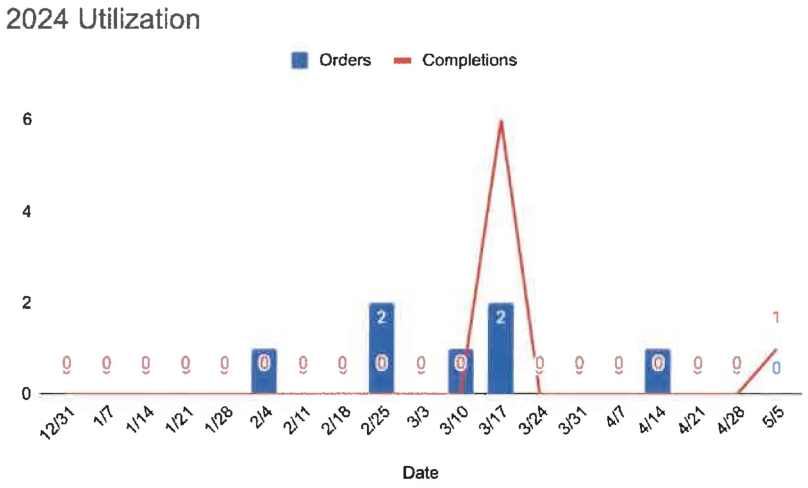
Galleri

2024 Utilization

Galleri Test Summary: 2024 Utilization

2024 Data Summary

- 986 Eligible
- 7 Galleri Orders
- 7 Galleri Completions
- .7% uptake
- 100 Net Promoter Score
- 100 Extremely Satisfied CSAT
- No Cancer Signals Detected



Important Safety Information

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. Galleri is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of Galleri is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

Results should be interpreted by a healthcare provider in the context of medical history, clinical signs and symptoms. A test result of "No Cancer Signal Detected" does not rule out cancer. A test result of "Cancer Signal Detected" requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer.

If cancer is not confirmed with further testing, it could mean that cancer is not present or testing was insufficient to detect cancer, including due to the cancer being located in a different part of the body. False-positive (a cancer signal detected when cancer is not present) and false-negative (a cancer signal not detected when cancer is present) test results do occur. Rx only.

Laboratory / Test Information

GRAIL's clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. The Galleri test was developed, and its performance characteristics were determined by GRAIL. The Galleri test has not been cleared or approved by the Food and Drug Administration. GRAIL's clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

GRAIL