

Pharmacogenomic testing for selected conditions

Draft evidence report: Comment and response

December 9, 2016

Health Technology Assessment Program (HTA)

Washington State Health Care Authority

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Pharmacogenomic Testing for Selected Conditions
Response to Public Comments on Draft Report

December 9, 2016

Prepared by:

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Response to Public Comments, Draft Report
Pharmacogenetic Testing for Selected Conditions

Hayes, Inc. is an independent vendor contracted to produce evidence assessment reports for the WA HTA program. For transparency, all comments received during the comments process are included in this response document.

Comments related to program decisions, processes, or other matters not pertaining to the evidence report are acknowledged through inclusion only. When comments cite evidence, the information is forwarded to the vendor for consideration in the evidence report. Please note that all received comments reflected the valued experiences and opinions of the commenter, none cited evidence from the report nor requested any changes to the draft evidence report.

This document responds to comments from the following parties:

- Jennie Brown, DNP, ARNP, PMHNP-BC, CFS, Swedish Medical Hospital
- Jeffry Jacobs, MD
- Angela Belcaster, ARNP, FNP, Lake Whatcom Center South Bay Health
- Elaine Ortman, ARNP, Psychiatric Nurse Practitioner, Discovery Behavioral Health System
- Nancy Pascua, P-ARNP, Sea Mar Community Health Centers, Behavioral Health
- Barbara Ruch, MN, ARNP, Psychiatric Nurse Practitioner, Sunrise Services, Inc
- Rahul Khurana, MD
- Susan Ehrlich, MD, Medical Director, Discovery Behavioral Healthcare
- Sandra Saffran, PhD, ARNP, Highland Hills Health & Counseling Center
- Ruth Rogers, ARNP, PMHNP-BC
- Jamie Walker, ARNP, Comprehensive Healthcare

Table 1 provides a summary of the comments with corresponding responses.

Table 1. Pharmacogenetic testing for selected conditions

Comment and Source	Response
November 10, 2016, e-mail from Jennie Brown, DNP, ARNP, PMHNP-BC, CFS (Swedish Medical Hospital)	
Pharmacogenetic testing allows us to recognize variations in the way patients metabolize their medications, thus allowing us to not only choose the appropriate medications when (common) genetic variations exist, but adjust doses based on how the patient will process the medication, be it to adjust above expected dosage for a rapid metabolizer, or be cautious with a slow metabolizer. Yes. This is particularly important when a patient has tried and failed multiple medications and is having no or unexpected responses to the medication. Absolutely. By knowing our patients' genetic variations in medication metabolism, we can more accurately select what will help. We can also more reliably avoid harm- for example, Genesight testing is able to indicate those more at risk for Stevens-Johnson syndrome from exposure to lamotrigine.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.
November 10, 2016, e-mail from Jeffrey Jacobs, MD (personal correspondence)	
I'd like to comment on my personal experience using pharmacogenetic testing to treat psychiatric disorders. As a Child, Adolescent, & Adult Psychiatrist working with Comprehensive Healthcare in Washington, I treat a broad spectrum of psychiatric disorders across the life-span. I am often in a position of trying to stabilize severely ill people who have failed multiple prior medication trials. Often, these people are at high risk for hospitalization or incarceration until stabilized. In my experience, I have seen the following benefits from the judicious use of Pharmacogenetic Testing: The ability to "cross-off" medication trials that are unlikely to work for a particular patient. This can be enormously helpful. Consider that each psychotropic medication trial is likely to take two months. There have been multiple occasions where I have gotten back test results showing that a particular person is unlikely to respond well to the next two medication trials I had planned on trying for that patient. That information has just saved that person 4-6 months of failed treatment, 4-6 months less suffering, and multiple additional visits - at a minimum. Over the long-run, getting these patient's to remission 4-6 months faster, is going to decrease hospitalizations, and save lives. Obtaining this test, has, in some cases, kept a patient from giving up on treatment. It is incredibly frustrating for a patient to go through one failed medication trial after another. Having some guidance available through pharmacogenetic testing has kept several patients of mine from giving up on treatment all-together. Knowledge obtained by these test results has helped me appropriately dose medication. I have used the information from these test results to go back to a "failed" medication trial with the knowledge that this person is	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.

Comment and Source	Response
an ultra-rapid metabolizer giving me the confidence to push the medication dose into a range that is actually effective for that particular patient. I can recall at least 3 occasions, 1 involving ADHD treatment, 1 involving treatment of panic disorder, and 1 involving treatment of major depressive disorder, where a previously "failed" medication turned out to be effective when dosed effectively based on knowledge obtained through these tests. Should this test be used haphazardly for every patient? No. Will this test help every time it's ordered? No. But is any test ordered in any branch of medicine always helpful? The fact is that we can't always know ahead of time when it will be a "life saver". Thank you for considering these comments and my experiences in your decision on whether to recommend coverage for this type of testing for our patients.	
November 10, 2016, e-mail from Angela Belcaster, ARNP, FNP (Lake Whatcom Center South Bay Health)	
I am a Family Nurse Practitioner currently seeing Medicaid managed care clients in an integrated behavioral health medical organization (Lake Whatcom Center) and in my private practice, South Bay Health. I have been using pharmacogenetics testing for several years and have reviewed the extensive literature surrounding it. I'd like to comment on HCA evaluation for coverage of these tests. In my practices I find great clinical utility for these tests when selecting medications and evaluating dosages for clients with virtually any psychiatric condition in which medication is indicated. As examples: If a client comes to me complaining that she/he has been on "many medications and nothing worked well", or "I have bad side effects from many medications" I am suspicious that they may not be processing these medications normally. I will frequently order testing for such individuals so that I am not guessing on this rather important fact. It helps me clear up from the start whether a client has a CYP or other drug metabolism pathway that is aberrantly slow or fast. If a client is already on a medication and is not responding, I may consider the test to find out if the medication is being processed too fast by the liver in which case a higher dose would be needed before an effect is seen). Without knowing how it's metabolized by this client, I am just guessing and may give up on a potentially useful medication, and switch to another (increasing cost, frustration, and morbidity for the patient while we guess at which drug or dose is right. I want to be clear- these tests don't tell me which drugs to prescribe at all. They inform my decisions regarding dosages, or which may be a better choice all other things being equal if a client metabolizes one drug normally versus one he/she does not. Genetic testing definitely informs the selection and dose of medication compared to usual care/no testing in those cases. It decreases time spent switching medications, ends up costing less, and gets clients to a state of better control more quickly.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.

Comment and Source	Response
I am certain that in practice genetic testing results in meaningful improvement in patient response to treatment. Many patients come to me after seeing other providers and having gone through numerous drug changes only to find out after testing that those drugs that either “didn’t work” or had too many side effects” were processed either too slow or too fast by the patient. Patients have little tolerance for guessing at medications when they are having side effects or are not getting a response and I know that they switch providers hoping to find someone who will “hit on the right med for me.” Genetic testing ends the guesswork. I don’t test everyone. I guide who to test based on their prior failed experiences with psychotropics or in whom starting a medication is critical and I don’t want to waste time guessing if they will metabolize it properly. Untreated depression and bipolar can be life threatening. As practitioners we always use our experience with medications, the indications, and client factors to prescribe. This test adds one more factor that contributes to our choices in prescribing. I am often relieved to see the results of a genetic test when I have been considering a medication and find out that a client wont process it normally, meaning it will behave in a way that I don’t expect as it is metabolized by that client. I can then consider something else, or stay with my initial choice, but at least I know what is happening and can make dose adjustments if indeed that is the best choice. Most of the clients that I have tested have one or more aberrant cyp pathways. They are often relieved to find out there is a way to identify how they metabolize medications and that these pathways can explain their prior failed experiences with medications. I would encourage the HCA to look closely at the experiences of practitioners in using these tests when making decisions about coverage. I firmly believe that they are extremely beneficial in guiding care, save money, time and morbidity in patients.	
November 14, 2016, e-mail from Elaine Ortman, ARNP, Psychiatric Nurse Practitioner (Discovery Behavioral Health System)	
I have been using this for about 5 years. It has been invaluable, particularly in clinical situations where clients have had multiple failed drug trials. In most cases, when I get the pharmacogenetic testing done I discover that most of the failed drug trials were due to either genetic mutations, or genetic inherited vulnerabilities to specific drugs. Clients who were on therapeutic dosages, with appropriate psychotropic medications either had no response, or so many side effects that they discontinued medications and were wary of trying another medication. For example, latest research indicates that within 2 weeks, 80% of antidepressant medications should be demonstrating some effectiveness. Choosing correct medication using the science of pharmacogenetics, not only avoids excessive drug trials expenses, and delays in treatment which results in the underlying illness getting worse. In my experience, previous to pharmacogenetics testing, medications were chosen based on side effect profile, FAMILIAL responses, when known. All of our medications have known effectiveness in treating mental health disorders. Given the 35% placebo (for adults) and 50% placebo (for child/adolescents) getting the most effective medication sooner vs later predicts the best treatment outcomes.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.

Comment and Source	Response
I use when appropriate, pharmacogenetics testing, for anyone who has had 1 or more failed drug trials, or show marked hypersensitivity to medications for the following psychiatric conditions: Major Depressive Disorder, Mood disorders, Psychotic Disorders, Anxiety Disorders, and ADHD. Please consider making this a covered service and part of the benefit package for members of the Washington State Health Authority.	
November 16, 2016, e-mail from Nancy Pascua, P-ARNP (Sea Mar Community Health Centers, Behavioral Health)	
I use genetic testing in my outpatient clinic to guide my medication treatment planning when a client has an unusual response to a medication or has tried and failed several medications in the same drug classification. The test provides me with medications that will not work for my clients as well as those most likely to be effective. When a medication is not metabolized properly by the liver, it causes side effects. I use the test to determine the most effective medications for depression, mood disorders, psychosis, anxiety and attention deficit disorder. I often find that I need to make medications changes and dose adjustments based on the genetic test. The test informs if a client needs more or less of a medication depending on their metabolism rate. I have found a marked improvement in response to medications when I use the genetic test to plan individual medications, particularly with clients who have tried and failed many medications in the past. I find genetic testing to be a valuable component in medication management.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.

Comment and Source	Response
November 15, 2016, Letter from Barbara Ruch, MN, ARNP (Psychiatric Nurse Practitioner, Sunrise Services, Inc) I would encourage you to include pharmacogenetic testing as a covered service for members of the Washington State Health Care Authority benefit plans. I do a fair amount of this testing with the clients I see at Sunrise Services. I feel it definitely helps me make better decisions about medications to prescribe. Clients frequently come in having been on a variety of medications in the past. It is a not an infrequent complaint of clients that “I was just a guinea pig... they kept trying one thing after another and nothing ever worked”. With the genetic testing, we can see issues with drug metabolism or see specific issues with genes that explain why previous medications have been ineffective. I find that these tests save time and frustrations for clients and myself. It generally takes an antidepressant 6-8 weeks to take effect and then possibly another 4-6 more weeks to push to maximal doses if the client isn’t responding. That amounts to 2 ½ - 3 months for each drug trial. We know from a variety of studies, that with each drug trial, the likelihood of clients responding to second, third, fourth, and more medications diminish with each trial. It makes sense to initiate treatment with medication that the genetic test shows has the best possibility of working rather than going through the insurance companies list of preferred medications in a trial and error fashion. Clients lose hope, become more depressed or drop out of care altogether feeling that nothing can help them. Using genetic testing also make sense financially. The cost of atypical antipsychotic medications can run between \$ 530.00-1072.00 per month. If a typical treatment trial takes 6-8 weeks, that is roughly \$795-1608 for a 6 week trial and \$1,060 – 2,144 for an 8 week trial. The pharmacogenetic testing cost less than one failed medication trial and can in fact focus on medication with the highest likelihood of being efficacious for the client. These tests <u>do</u> make a difference for my clients. When I discuss the possibility of having this test available to clients they give a sigh of relief and then ask why this hasn’t been done in the past, as this would have saved them countless medication trials and adverse effects related to medications. As a prescriber, I feel blindfolded when this option is not available to me. The test allows me to truly individualize care to my clients, prescribe medications with the greatest likelihood of alleviating their symptoms, and of alleviating their suffering. I urge you to continue to provide coverage for pharmacogenetic testing.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.

Comment and Source	Response
November 17, 2016, Letter from Rahul Khurana, MD (personal correspondence)	
I am a psychiatrist in private practice who has been utilizing the GeneSight pharmacogenomic testing since September 2015. I have so far ordered it almost 200 times. This has been a revolutionary tool in helping me to practice precision medicine for my vulnerable patient population. It has allowed me to discover when a patient's current medications are actually making them worse and in some patients, reduced the number of medications they are on. In some of these cases, I would not have figured this out without the testing. In others it helped me find the appropriate medications faster than with trial and error. It has also allowed me to pick pharmacotherapeutic options that I would most likely not have picked without the test results. Patients & families have been more than appreciative of this new test. I strongly urge you to provide coverage for this test so it can be an affordable option for all patients. Feel free to contact me with any questions. Thank you.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.
November 21, 2016, email from Susan Ehrlich, MD (Medical Director, Discovery Behavioral Healthcare)	
I would like to comment in favor of HCA coverage for Genesight testing of psychotropic medication metabolic capacity. Our mental health agency has utilized this testing extensively over the past 1 ½ years. The literature supporting the testing methods as well as the clinical algorithms for using the results, are sound. The genetic testing results are used to choose medications that patients are most likely to tolerate well and for which they are likely to achieve serum levels that afford symptom relief. The testing is used for initial med starts and for treatment-resistant situations. It is useful for a variety of diagnoses including mood disorders, psychotic disorders, anxiety, and post traumatic stress disorder. Medication selection and dosing are changed in response to the testing, which adds to the information from clinical exams, screening tests, and patient reports. We find that the testing reduces adverse med effects, futile med trials, and prolonged suffering due to ineffective med choices. I hope that the decision not to allow coverage for the Genesight testing, is reversed so that more patients will be able to utilize it.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.

Comment and Source	Response
November 17, 2016, email from Sandra Saffran, PhD, ARNP (Highland Hills Health & Counseling Cntr) My name is Sandra Saffran PhD, ARNP and I am a psychiatric nurse practitioner in Yakima, Washington. I have 40+ years of experience in private practice, nursing and public health and hold a Doctorate in Clinical Psychology. I am writing to provide my comments on the clinical utility of genetic testing and how pharmacogenetic testing has made a positive impact on my practice and on my client population. Many patients who seek the care of a mental health specialist have been through the psychiatric “ringer”, so-to-say. With primary care providers prescribing psychotropic medication, many patients who seek the care of a specialist tend to have a complex presentation—and many have already tried and failed numerous medications. Additionally, the comorbid presence of medical diagnoses with psychiatric diagnoses leads individuals to require numerous medications to treat various conditions which can lead to increased medication failures due to the interactions between medications and the overwhelming list of side effects. This repeated failure of medication efficacy severely detracts a patient’s perceived ability to get better, leading many to feel broken, irreparably “flawed”. After performing the GeneSight tests of medication metabolism on hundreds of my patients, I have seen how unique the testing is in its ability to restore faith in the ability to get well. Understanding how and why past medications failed has allowed patients to experience medication that actually treats their diagnoses without the burden of adverse events. In addition to medication metabolism, pharmacogenetic testing provides insight into various neurotransmitter imbalances which can be specifically targeted with medication to alleviate psychiatric symptoms. For example, one receptor has a critical role in regulating neurotransmitter release for sympathetic nerves and for adrenergic neurons in the central nervous system. Patients with a reduced response of this receptor tend to suffer from a prolonged state of fight-or-flight anxiety and sleep problems due to autonomic arousal.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.

Comment and Source	Response
Instead of loading these patients up with sedatives such as Xanax and Ambien, which carry risks of overdose and addiction, I can prescribe medications that target that specific imbalance, correcting the problem. Furthermore, the ability provided by pharmacogenetic testing to choose and dose medication properly—if utilized in a patient who hasn't yet given up hope on the journey to mental health wellness—has the potential to result in uniquely impactful clinical improvement. My patients rarely encounter adverse events. This allows patients to regain functional status in less time, with fewer setbacks in their occupational, academic and social lives. The genetic testing has also eliminated the trial and error approach to psychotropic prescribing. Through performing the testing on patients who are already on medication, I have found that many (if not the majority) are on medication that clashes with their genetic profile of medication metabolism. Invariably, many of these patients have been referred due to ineffective psychotropic medication. Thus, I have found pharmacogenetic testing to be invaluable in the selection and dosing of medications. The testing has also aided in efforts to coordinate care with a given patient's multiple providers/prescribers. As mentioned previously, many of my patients are on numerous medications (15-20+) and all of their providers are able to utilize the testing even though it is tailored to psychiatry. In addition to myself, many patient's primary care physicians or various specialists change medications guided by the results of the pharmacogenetic testing. Personally, I see the pharmacogenomics testing as the future of psychiatry, if not prescribing in general. In utilizing the GeneSight tests, I have been able to expect much better results from psychotropic prescribing by the near elimination of adverse events and no longer having to rely on the trial and error method of prescribing.	

Comment and Source	Response
November 21, 2016, letter from Ruth Rogers, ARNP, PMHNP-BC (personal correspondence)	
I am writing in support of continued coverage for the GeneSight psychotropic test. I have been using the test for two years and have tested over 125 patients, and it has proved to be extremely helpful for my practice. It has proven to help guide patient treatment initially by helping avoid medications that are less likely to work as well as selecting appropriate doses to avoid side effects. Additionally it helps patients in the long term as every time I need to make a medication change, I can refer back to the test result for optimal medications and doses. Many of my chronically mentally ill patients have had remarkable improvements once moved to medications more appropriate for them, and most are doing better than they have in years. In my experience patients given the test have had more success achieving relief and avoiding side effects compared to patients who have not received genetic testing. There have been countless examples where I have found the right treatment for a patient who had not experienced any relief for many years and helped reduce the amount of medications they were taking, something that was unsuccessful before the test. If this testing is taken away for patients it will require more failed medications trials, increased numbers of inpatient hospitalizations, lost housing placements due to illness-related behaviors, and increased time for them to find the optimal medication and achieve relief. I strongly encourage you to keep this test available for our patients to help guide treatment.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.
November 21, 2016, email from Jamie Walker, ARNP (Comprehensive Healthcare)	
I am writing to comment on the recommendation to not include pharmacogenetic testing for selected conditions in next year's coverage. I frequently use pharmacogenetic testing in my mental health practice to determine if there are issues with the way patient's bodies metabolize medications. This helps me determine the type of medication, how to dose it, and choose medications that are more likely to have greater, more individualized clinical responses in the treatment of conditions such as depression, anxiety, Bipolar Disorder, psychotic disorders, and ADHD. In many cases, it also helps patients have greater confidence in their medications. I use it in all age ranges, including children through senior adults. I have noticed that it helps decrease frequent changing of medications since it eliminates the need to try and fail several different medications to find one that actually works. It also helps decrease dosage changes based on the results it provides, and it has overall decreased the number of adverse events patients experience since we are tailoring the medications to their individual results. I feel it is a valuable tool for psychiatric prescribers, and if not covered, may result in higher healthcare costs overall.	Thank you for your comment, your review of the draft report, and for sharing your clinical experience related to this topic.

From: [Jennie Brown](#)
To: [HCA ST Health Tech Assessment Prog](#)
Subject: Pharmacogenetic testing for selected conditions
Date: Thursday, November 10, 2016 10:07:45 AM

1. Pharmacogenetic testing allows us to recognize variations in the way patients metabolize their medications, thus allowing us to not only choose the appropriate medications when (common) genetic variations exist, but adjust doses based on how the patient will process the medication, be it to adjust above expected dosage for a rapid metabolizer, or be cautious with a slow metabolizer.
2. Yes. This is particularly important when a patient has tried and failed multiple medications and is having no or unexpected responses to the medication.
3. Absolutely. By knowing our patients' genetic variations in medication metabolism, we can more accurately select what will help. We can also more reliably avoid harm- for example, Genesight testing is able to indicate those more at risk for Stevens-Johnson syndrome from exposure to lamotrigine.

Jennie Brown, DNP, ARNP, PMHNP-BC
CFS-Metro
Voicemail: 425-653-4958
jennieb@smh.org

From: [Jeff Jacobs](#)
To: [HCA ST Health Tech Assessment Prog](#)
Subject: Pharmacogenetic testing for selected conditions
Date: Thursday, November 10, 2016 12:40:13 PM
Attachments: [image.png](#)

Hello,

I'd like to comment on my personal experience using pharmacogenetic testing to treat psychiatric disorders. As a Child, Adolescent, & Adult Psychiatrist working with Comprehensive Healthcare in Washington, I treat a broad spectrum of psychiatric disorders across the life-span. I am often in a position of trying to stabilize severely ill people who have failed multiple prior medication trials. Often, these people are at high risk for hospitalization or incarceration until stabilized. In my experience, I have seen the following benefits from the judicious use of Pharmacogenetic Testing:

1. The ability to "cross-off" medication trials that are unlikely to work for a particular patient. This can be enormously helpful. Consider that each psychotropic medication trial is likely to take two months. There have been multiple occasions where I have gotten back test results showing that a particular person is unlikely to respond well to the next two medication trials I had planned on trying for that patient. That information has just saved that person 4-6 months of failed treatment, 4-6 months less suffering, and multiple additional visits - at a minimum. Over the long-run, getting these patient's to remission 4-6 months faster, is going to decrease hospitalizations, and save lives.

2. Obtaining this test, has, in some cases, kept a patient from giving up on treatment. It is incredibly frustrating for a patient to go through one failed medication trial after another. Having some guidance available through pharmacogenetic testing has kept several patients of mine from giving up on treatment all-together.

3. Knowledge obtained by these test results has helped me appropriately dose medication. I have used the information from these test results to go back to a "failed" medication trial with the knowledge that this person is an ultra-rapid metabolizer giving me the confidence to push the medication dose into a range that is actually effective for that particular patient. I can recall at least 3 occasions, 1 involving ADHD treatment, 1 involving treatment of panic disorder, and 1 involving treatment of major depressive disorder, where a previously "failed" medication turned out to be effective when dosed effectively based on knowledge obtained through these tests.

Should this test be used haphazardly for every patient? No. Will this test help every time it's ordered? No. But is any test ordered in any branch of medicine always helpful? The fact is that we can't always know ahead of time when it will be a "life saver". Thank you for considering these comments and my experiences in your decision on whether to recommend coverage for this type of testing for our patients.

Sincerely,



Jeffrey A Jacobs, MD

From: [Belcaster, Angela M.](#)
To: [HCA ST Health Tech Assessment Prog](#)
Subject: Pharmacogenetic testing comments
Date: Thursday, November 10, 2016 3:41:35 PM

Hello,

I am a Family Nurse Practitioner currently seeing Medicaid managed care clients in an integrated behavioral health medical organization (Lake Whatcom Center) and in my private practice, South Bay Health.

I have been using pharmacogenetics testing for several years and have reviewed the extensive literature surrounding it.

I'd like to comment on HCA evaluation for coverage of these tests.

1. In my practices I find great clinical utility for these tests when selecting medications and evaluating dosages for clients with virtually any psychiatric condition in which medication is indicated. As examples: If a client comes to me complaining that she/he has been on "many medications and nothing worked well", or "I have bad side effects from many medications" I am suspicious that they may not be processing these medications normally. I will frequently order testing for such individuals so that I am not guessing on this rather important fact. It helps me clear up from the start whether a client has a CYP or other drug metabolism pathway that is aberrantly slow or fast. If a client is already on a medication and is not responding, I may consider the test to find out if the medication is being processed too fast by the liver (in which case a higher dose would be needed before an effect is seen). Without knowing how its metabolized by this client, I am just guessing and may give up on a potentially useful medication, and switch to another (increasing cost, frustration, and morbidity for the patient while we guess at which drug or dose is right. I want to be clear- these tests don't tell me which drugs to prescribe at all. They inform my decisions regarding dosages, or which may be a better choice all other things being equal if a client metabolizes one drug normally versus one he/she does not.
2. Genetic testing definitely informs the selection and dose of medication compared to usual care/no testing in those cases. It decreases time spent switching medications, ends up costing less, and gets clients to a state of better control more quickly.
3. I am certain that in practice genetic testing results in meaningful improvement in patient response to treatment. Many patients come to me after seeing other providers and having gone through numerous drug changes only to find out after testing that those drugs that either "didn't work" or had too many side effects" were processed either too slow or too fast by the patient. Patients have little tolerance for guessing at medications when they are having side effects or are not getting a response and I know that they switch providers hoping to find someone who will "hit on the right med for me." Genetic testing ends the guesswork. I don't test everyone. I guide who to test based on their prior failed experiences with psychotropics or in whom starting a medication is critical and I don't want to waste time guessing if they will metabolize it properly. Untreated depression and bipolar can be life threatening. As practitioners we always use our experience with medications, the indications, and client factors to prescribe. This test adds one more factor that contributes to our choices in prescribing. I am often relieved to see the results of a genetic test when I have been considering a medication and find out that a client wont process it normally, meaning it will behave in a way that I don't expect as it is metabolized by that client. I can then consider

something else, or stay with my initial choice, but at least I know what is happening and can make dose adjustments if indeed that is the best choice.

4. Most of the clients that I have tested have one or more aberrant cyp pathways. They are often relieved to find out there is a way to identify how they metabolize medications and that these pathways can explain their prior failed experiences with medications. I would encourage the HCA to look closely at the experiences of practitioners in using these tests when making decisions about coverage. I firmly believe that they are extremely beneficial in guiding care, save money, time and morbidity in patients.

Thank you,

Angela Belcaster ARNP, FNP

Lake Whatcom Center

South Bay Health

Bellingham, WA

From: [Elaine Ortman](#)
To: [HCA ST Health Tech Assessment Prog](#)
Subject: Pharmacogenetic testing for selected conditions
Date: Monday, November 14, 2016 5:47:02 PM

To Whom It May Concern:

I have been using this for about 5 years. It has been invaluable, particularly in clinical situations where clients have had multiple failed drug trials. In most cases, when I get the pharmacogenetic testing done I discover that most of the failed drug trials were due to either genetic mutations, or genetic inherited vulnerabilities to specific drugs. Clients who were on therapeutic dosages, with appropriate psychotropic medications either had no response, or so many side effects that they discontinued medications and were wary of trying another medication. For example, latest research indicates that within 2 weeks, 80% of antidepressant medications should be demonstrating some effectiveness. Choosing correct medication using the science of pharmacogenetics, not only avoids excessive drug trials expenses, and delays in treatment which results in the underlying illness getting worse. In my experience, previous to pharmacogenetics testing, medications were chosen based on side effect profile, FAMILIAL responses, when known. All of our medications have known effectiveness in treating mental health disorders. Given the 35% placebo (for adults) and 50% placebo (for child/adolescents) getting the most effective medication sooner vs later predicts the best treatment outcomes.

I use when appropriate, pharmacogenetics testing, for anyone who has had 1 or more failed drug trials, or show marked hypersensitivity to medications for the following psychiatric conditions: Major Depressive Disorder, Mood disorders, Psychotic Disorders, Anxiety Disorders, and ADHD.

Please consider making this a covered service and part of the benefit package for members of the Washington State Health Authority.

Thank you for your consideration.

Elaine Ortman ARNP
Psychiatric Nurse Practitioner
Discovery Behavioral Health System

From: [Nancy Pascua](#)
To: [HCA ST Health Tech Assessment Prog](#)
Subject: Pharmacogenetic testing for selected conditions
Date: Wednesday, November 16, 2016 10:21:21 AM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)

I use genetic testing in my outpatient clinic to guide my medication treatment planning when a client has an unusual response to a medication or has tried and failed several medications in the same drug classification. The test provides me with medications that will not work for my clients as well as those most likely to be effective. When a medication is not metabolized properly by the liver, it causes side effects. I use the test to determine the most effective medications for depression, mood disorders, psychosis, anxiety and attention deficit disorder.

I often find that I need to make medications changes and dose adjustments based on the genetic test. The test informs if a client needs more or less of a medication depending on their metabolism rate.

I have found a marked improvement in response to medications when I use the genetic test to plan individual medications, particularly with clients who have tried and failed many medications in the past.

I find genetic testing to be a valuable component in medication management.



Nancy C. Pascua | **P-ARNP**
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Connect with us on ☐ & ☐

Washington State Health Care Authority

November 15, 2016

Re: Pharmacogenetic testing for selected conditions

To whom it may concern,

I would encourage you to include pharmacogenetic testing as a covered service for members of the Washington State Health Care Authority benefit plans. I do a fair amount of this testing with the clients I see at Sunrise Services. I feel it definitely helps me make better decisions about medications to prescribe.

Clients frequently come in having been on a variety of medications in the past. It is not an infrequent complaint of clients that "I was just a guinea pig... they kept trying one thing after another and nothing ever worked". With the genetic testing, we can see issues with drug metabolism or see specific issues with genes that explain why previous medications have been ineffective.

I find that these tests save time and frustrations for clients and myself. It generally takes an antidepressant 6-8 weeks to take effect and then possibly another 4-6 more weeks to push to maximal doses if the client isn't responding. That amounts to 2 ½ - 3 months for each drug trial. We know from a variety of studies, that with each drug trial, the likelihood of clients responding to second, third, fourth, and more medications diminish with each trial. It makes sense to initiate treatment with medication that the genetic test shows has the best possibility of working rather than going through the insurance companies list of preferred medications in a trial and error fashion. Clients lose hope, become more depressed or drop out of care altogether feeling that nothing can help them.

Using genetic testing also make sense financially. The cost of atypical antipsychotic medications can run between \$ 530.00-1072.00 per month. If a typical treatment trial takes 6-8 weeks, that is roughly \$795-1608 for a 6 week trial and \$1,060 – 2,144 for an 8 week trial. The pharmacogenetic testing cost less than one failed medication trial and can in fact focus on medication with the highest likelihood of being efficacious for the client.

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These tests do make a difference for my clients. When I discuss the possibility of having this test available to clients they give a sigh of relief and then ask why this hasn't been done in the past, as this would have saved them countless medication trials and adverse effects related to medications. As a prescriber, I feel blindfolded when this option is not available to me.

The test allows me to truly individualize care to my clients, prescribe medications with the greatest likelihood of alleviating their symptoms, and of alleviating their suffering. I urge you to continue to provide coverage for pharmacogenetic testing.

Sincerely,

 *Barbara Ruch*

Barbara Ruch, M.N., ARNP
Psychiatric Nurse Practitioner
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November 17, 2016

To Washington State Health Care Authority:

I am a psychiatrist in private practice who has been utilizing the GeneSight pharmacogenomic testing since September 2015. I have so far ordered it almost 200 times. This has been a revolutionary tool in helping me to practice precision medicine for my vulnerable patient population. It has allowed me to discover when a patient's current medications are actually making them worse and in some patients, reduced the number of medications they are on. In some of these cases, I would not have figured this out without the testing. In others it helped me find the appropriate medications faster than with trial and error. It has also allowed me to pick pharmacotherapeutic options that I would most likely not have picked without the test results. Patients & families have been more than appreciative of this new test. I strongly urge you to provide coverage for this test so it can be an affordable option for all patients. Feel free to contact me with any questions. Thank you.

Sincerely,

A black rectangular redaction box covering the signature of Rahul Khurana, M.D.

Rahul Khurana, M.D.

From: [susan ehrlich](#)
To: [HCA ST Health Tech Assessment Prog](#)
Subject: pharmacogenetic testing for selected conditions
Date: Monday, November 21, 2016 11:37:53 AM

Good morning,

I would like to comment in favor of HCA coverage for Genesight testing of psychotropic medication metabolic capacity.

Our mental health agency has utilized this testing extensively over the past 1 ½ years.

The literature supporting the testing methods as well as the clinical algorithms for using the results, are sound.

The genetic testing results are used to choose medications that patients are most likely to tolerate well and for which they are likely to achieve serum levels that afford symptom relief. The testing is used for initial med starts and for treatment-resistant situations. It is useful for a variety of diagnoses including mood disorders, psychotic disorders, anxiety, and post traumatic stress disorder. Medication selection and dosing are changed in response to the testing, which adds to the information from clinical exams, screening tests, and patient reports.

We find that the testing reduces adverse med effects, futile med trials, and prolonged suffering due to ineffective med choices.

I hope that the decision not to allow coverage for the Genesight testing, is reversed so that more patients will be able to utilize it.

Thank you!

Susan Ehrlich, MD
Medical Director
Discovery Behavioral Healthcare
(360)385-0321 ext 151



4601 Tieton Drive • Yakima, WA 98908 • Phone: [REDACTED]

November 17, 2016

Washington State Health Care Authority
626 8th Ave SE
Olympia, WA 98501

Re: Pharmacogenetic testing for selected conditions

Dear Sir or Madam,

My name is Sandra Saffran PhD, ARNP and I am a psychiatric nurse practitioner in Yakima, Washington. I have 40+ years of experience in private practice, nursing and public health and hold a Doctorate in Clinical Psychology. I am writing to provide my comments on the clinical utility of genetic testing and how pharmacogenetic testing has made a positive impact on my practice and on my client population.

Many patients who seek the care of a mental health specialist have been through the psychiatric "ringer", so-to-say. With primary care providers prescribing psychotropic medication, many patients who seek the care of a specialist tend to have a complex presentation—and many have already tried and failed numerous medications. Additionally, the comorbid presence of medical diagnoses with psychiatric diagnoses leads individuals to require numerous medications to treat various conditions which can lead to increased medication failures due to the interactions between medications and the overwhelming list of side effects. This repeated failure of medication efficacy severely detracts a patient's perceived ability to get better, leading many to feel broken, irreparably "flawed".

After performing the GeneSight tests of medication metabolism on hundreds of my patients, I have seen how unique the testing is in its ability to restore faith in the ability to get well. Understanding how and why past medications failed has allowed patients to experience medication that actually treats their diagnoses without the burden of adverse events.

In addition to medication metabolism, pharmacogenetic testing provides insight into various neurotransmitter imbalances which can be specifically targeted with medication to alleviate psychiatric symptoms. For example, one receptor has a critical role in regulating neurotransmitter release for sympathetic nerves and for adrenergic neurons in the central nervous system. Patients with a reduced response of this receptor tend to suffer from a prolonged state of fight-or-flight anxiety and sleep problems due to autonomic arousal.

Instead of loading these patients up with sedatives such as Xanax and Ambien, which carry risks of overdose and addiction, I can prescribe medications that target that specific imbalance, correcting the problem.

Furthermore, the ability provided by pharmacogenetic testing to choose and dose medication properly—if utilized in a patient who hasn't yet given up hope on the journey to mental health wellness—has the potential to result in uniquely impactful clinical improvement. My patients rarely encounter adverse events. This allows patients to regain functional status in less time, with fewer setbacks in their occupational, academic and social lives.

The genetic testing has also eliminated the trial and error approach to psychotropic prescribing. Through performing the testing on patients who are already on medication, I have found that many (if not the majority) are on medication that clashes with their genetic profile of medication metabolism. Invariably, many of these patients have been referred due to ineffective psychotropic medication. Thus, I have found pharmacogenetic testing to be invaluable in the selection and dosing of medications. The testing has also aided in efforts to coordinate care with a given patient's multiple providers/prescribers. As mentioned previously, many of my patients are on numerous medications (15-20+) and all of their providers are able to utilize the testing even though it is tailored to psychiatry. In addition to myself, many patient's primary care physicians or various specialists change medications guided by the results of the pharmacogenetic testing.

Personally, I see the pharmacogenomics testing as the future of psychiatry, if not prescribing in general. In utilizing the GeneSight tests, I have been able to expect much better results from psychotropic prescribing by the near elimination of adverse events and no longer having to rely on the trial and error method of prescribing.

I may be reached at (509)452-2404 with any questions or concerns that may arise in your assessment.

Respectfully submitted,



Phd ARNP

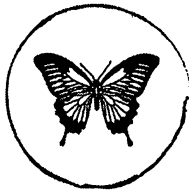
Sandra K. Saffran PhD, ARNP

PhD Clinical Psychology

Board Certified Clinical Nurse Specialist Adult Psychiatric/Mental Health

Board Certified Clinical Nurse Specialist Child/Adolescent Psychiatric/Mental Health

bg



VANCOUVER INTEGRATIVE COUNSELING

Ruth Rogers, ARNP, PMHNP-BC

1711 Main Street, Vancouver, WA 98660
[REDACTED]

November 21, 2016

Dear Washington State Health Care Authority,

I am writing in support of continued coverage for the GeneSight psychotropic test. I have been using the test for two years and have tested over 125 patients, and it has proved to be extremely helpful for my practice. It has proven to help guide patient treatment initially by helping avoid medications that are less likely to work as well as selecting appropriate doses to avoid side effects. Additionally it helps patients in the long term as every time I need to make a medication change, I can refer back to the test result for optimal medications and doses. Many of my chronically mentally ill patients have had remarkable improvements once moved to medications more appropriate for them, and most are doing better than they have in years.

In my experience patients given the test have had more success achieving relief and avoiding side effects compared to patients who have not received genetic testing. There have been countless examples where I have found the right treatment for a patient who had not experienced any relief for many years and helped reduce the amount of medications they were taking, something that was unsuccessful before the test. If this testing is taken away for patients it will require more failed medications trials, increased numbers of inpatient hospitalizations, lost housing placements due to illness-related behaviors, and increased time for them to find the optimal medication and achieve relief. I strongly encourage you to keep this test available for our patients to help guide treatment.

Sincerely,

[REDACTED], ARNP

*Ruth Rogers, ARNP, PMHNP-BC
Vancouver Integrative Counseling*

From: [Jamie Walker](#)
To: [HCA ST Health Tech Assessment Prog](#)
Subject: pharmacogenetic testing for selected conditions
Date: Monday, November 21, 2016 4:44:22 PM
Attachments: [image001.png](#)

Hello,

I am writing to comment on the recommendation to not include pharmacogenetic testing for selected conditions in next year's coverage.

I frequently use pharmacogenetic testing in my mental health practice to determine if there are issues with the way patient's bodies metabolize medications. This helps me determine the type of medication, how to dose it, and choose medications that are more likely to have greater, more individualized clinical responses in the treatment of conditions such as depression, anxiety, Bipolar Disorder, psychotic disorders, and ADHD. In many cases, it also helps patients have greater confidence in their medications. I use it in all age ranges, including children through senior adults.

I have noticed that it helps decrease frequent changing of medications since it eliminates the need to try and fail several different medications to find one that actually works. It also helps decrease dosage changes based on the results it provides, and it has overall decreased the number of adverse events patients experience since we are tailoring the medications to their individual results. I feel it is a valuable tool for psychiatric prescribers, and if not covered, may result in higher healthcare costs overall.

Jamie Walker

Advanced Registered Nurse Practitioner



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