North Carolina State Health Plan
FOR TEACHERS AND STATE EMPLOYEES
A Division of the Department of State Treasurer

Board of Trustees Meeting
Thursday, August 27, 2015
4:00 p.m. – 6:00 p.m.

1.	Welcome	Janet Cowell, Chair
2.	Conflict of Interest Statement	Janet Cowell, Chair
3.	Review of Minutes ***(Requires Board Approval)***	Janet Cowell, Chair
	A. May 22, 2015	
	B. July 8, 2015 Teleconference	
4.	Requests for Benefit Changes - Pursuant to Article IV, Section 2 and Article V, Section 10 of the Bylaws of the State Health Plan Board of Trustees	
	A. UNC Hospitals, Bone Marrow Transplant Program State Health Plan Member	Susan Elizabeth Sharf Program Director
	B. NC Association of Acupuncture and Oriental Medicine	Chris Helmstetter, LAc Director Government Affairs
	C. State Employees Association of North Carolina	Chuck Stone Director of Operations
5.	Program Updates	
	A. Pharmacy & Therapeutics Committee Meeting Summary	Glenda Adams
	B. Wellness Wins Pilot Update	Christine Allison
	C. Patient Centered Medical Home Pilot Update	David Boerner

Our mission is to improve the health and health care of North Carolina teachers, state employees, retirees, and their dependents, in a financially sustainable manner, thereby serving as a model to the people of North Carolina for improving their health and well-being.

North Carolina State Health Plan
FOR TEACHERS AND STATE EMPLOYEES
A Division of the Department of State Treasurer

Board of Trustees Meeting
Friday, August 28, 2015
9:00 a.m. – 3:00 p.m.

(9:05 a.m. to 10:00 a.m. – Executive Session)

1. Welcome — Janet Cowell, Chair

2. Conflict of Interest Statement — Janet Cowell, Chair

3. **Executive Session (for Board Members and Required Staff only)** — Janet Cowell, Chair
   Pursuant to: G.S. 143-318.11 and G.S. 132-1.2
   - A. Consultation with Legal Counsel – Contract Issue — Lotta Crabtree
     (G.S. §143.318.11(a)(3) and G.S. § 132-1.2)

4. Executive Administrator Report
   - A. Introduction of New Staff — Mona Moon
     Sandy Wolf, Director of Pharmacy Benefits
   - B. Contracting and Vendor Partnerships
     - i. Eligibility & Enrollment Services (EES) — Mona Moon
     - ii. EES Services Transition Plan — Caroline Smart
     - iii. EES Contract Approval ***(Requires Board Approval)*** — Lotta Crabtree

5. Legislative Update — Tom Friedman
   - A. State Budget
   - B. State Health Plan Related Legislation
   - C. Local Government Participation in the State Health Plan
   - D. Joint Legislative Program Evaluation Oversight Committee – Report Number 2015-05, Retiree Health, July 27, 2015

6. Financial Report, Forecasting and Monitoring — Mark Collins

   A. Actuarial Valuation of Retired Employees' Health Benefits – Other Postemployment Benefits (OPEB) as of Dec 31, 2014

   B. 2014-15 State Fiscal Year End Report

   C. June 2015 Financial Report

   D. CY 2015 2nd Quarter Actuarial Forecast Update — Mark Collins, Tom Friedman

Lunch

7. Benefit Design, Plan Options and Premiums

   A. Delay Tobacco Attestation Requirement for 70/30 Plan ***(Requires Board Approval)*** — Mona Moon

   B. 2016 Premium Contribution Rates ***(Requires Board Approval)*** — Tom Friedman

   C. Out of Network Lab Benefit ***(Requires Board Approval)*** — Caroline Smart

   D. Health Engagement Program ***(Requires Board Approval)*** — Nidu Menon, Angie Wester

   E. Diabetes Primary Prevention Program — Nidu Menon

8. Member Experience and Communications Update — Beth Horner

Break

9. Member and Public Comment Period

10. Adjourn — Janet Cowell, Chair

Next Regularly Scheduled Meeting: November 19, 4–6 p.m. and November 20, 9 a.m. – 3 p.m.

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APPENDIX A

Request Form for Board of Trustee Consideration of a Change to SHP Benefits

This form is to be used by individuals or groups that would like to propose new benefits coverage or request changes to benefits already covered by the State Health Plan. Please read the Procedure – Requests for Benefits Changes, SHP-PRO-7001-SHPfor more information regarding these types of requests.

Please submit completed forms by email to SHP.Board@nctreasurer.com or mail to NC State Health Plan Board of Trustees, 4901 Glenwood Avenue, Suite 300, Raleigh, NC 27612-3638.

Name of Requestor: Susan Elizabeth Sharf

Contact Information (*phone, email, mailing address):*

919-408-1809 / asharf@triad.rr.com / 3513 Bentridge Drive Mebane, NC 27302

Requested Change in Benefits Coverage: increase in donor search coverage for BMT patients

Reason for Request: current $10,000 maximum does not cover HLA typing costs for this need

Proposed Effective Date of Change: ASAP

Supporting Documentation (*Please provide documents to support your request; examples include research or studies regarding medical services, treatment or procedures, fiscal impact analyses if available, or petitions from members.*):

Would you like to speak with the Board of Trustees about this issue at a Board of Trustees meeting? yes/can arrange for Nat'l Marrow Donor Program personnel to speak as well

The Board of Trustees reviews select requests annually at a regularly scheduled Board of Trustee meeting. For calendar year 2013, requests will be reviewed at the November meeting. For calendar year 2014, requests will be reviewed at the July meeting. Review of requests in no way obligates the State Treasurer to make changes to benefits.

TO: NC Board of Trustees **DATE:** June 8, 2015

RE: Bone Marrow Transplant Donor Search Coverage Benefits

As a subscriber to the State Employee Health Plan, **I would like the Board to consider raising the $10,000 donor search coverage limit for bone marrow transplant recipients**. This is not a sufficient amount to cover the donor search costs for those candidates who are not fortunate enough to find a match within their own family.

To help explain my rationale for this request, I have attached several documents for review. In addition, I will outline my concerns with this benefit coverage as follows:

Being a donor match for a bone marrow transplant (BMT) recipient is different from those who need to receive a solid organ transplant (heart, kidney, lung, etc.). For solid organ transplants, 'matching' requires that both the donor and the recipient must have blood types that are compatible just like a blood transfusion. For BMT, however, there are markers on our white blood cells called Human Leukocyte Antigens (HLA) which must match to a certain degree in order for a donor to be considered. The better the "match grade" is, the better the chance that the BMT will be successful.

We all have only a 30% chance of finding a suitably matched donor amongst our full siblings (same mother and father) based upon the way our DNA is mapped. If a patient is not fortunate enough to find a match within their family or has no full siblings to type, the search turns to finding an unrelated donor within a registry such as The National Marrow Donor Program (NMDP). The success of finding an unrelated donor depends solely upon finding identical ethnicity within the HLA markers that are passed on from generation to generation in someone with whom you are not related. As an example, I have very common HLA markers for Caucasians from northern Europe; however, one HLA marker that has been passed along to me is of American Indian ethnicity. This would mean that the chances of my finding a fully matched unrelated donor decreases significantly unless someone who shares this exact combination of ethnicities on their HLA markers happens to be listed as a donor on a public registry. For those who have multiple ethnicities, the probability of finding a donor decreases which means a donor search may be more difficult, ultimately take longer and cumulatively cost more.

The current donor coverage that the State Health Plan offers *could* be adequate to cover search expenses if one were lucky enough to find a donor within their family. However, if an unrelated donor search needs to occur, this funding will *not* be sufficient - especially when there are multiple family members to type first which would exhaust the $10,000 benefit quickly. HLA typing can cost $2,500-$3,500 per donor to complete which would be enough to test only two to three siblings. My concern is that other insurance companies, such as BCBS, offer their subscribers unlimited donor search coverage and it seems that our North Carolina teachers, firefighters, policemen/women as well as all other state employees deserve similar benefits. Increasing the dollar amount available for this specific part of our coverage will not affect the majority of our State Health Plan members; however, this modification would be significant for those who must undergo a BMT. Families can become financially devastated as a result of undergoing a BMT and an approval to increase these benefits would certainly be helpful for those subscribers directly affected.

Thank you for your consideration and I appreciate your time in reading this proposal.

Very truly yours,

Susan Sharf 919-408-1809

Susan Sharf

NATIONAL MARROW DONOR PROGRAM® BE THE MATCH®

Benefit Design for HCT

Recommendations for designing an effective health insurance benefit set for hematopoietic cell transplantation (HCT)

Benefit Category	Recommendations
Allogeneic Donor Search Process	**Recommendation**: Full coverage of tissue typing of patient, potential related donors, and unrelated donors through Be The Match® or other approved registry. **Rationale**: 70% of patients do not have a fully matched sibling donor. Limiting or excluding search coverage delays transplant and can result in unnecessary and costly complications. Information about average costs and processes can be found at Payor.BeTheMatchClinical.org **Administrative Guidance:** Place search and procurement benefits in separate categories to ensure availability for each stage. Requiring proof of donor insurance policy denial for typing will unnecessarily delay the process; all policies prohibit coverage of costs when a member is acting as a donor. The Medicare claims processing manual indicates that donors should never be billed for transplant costs.
Cell Procurement or Acquisition	**Recommendation**: Full coverage of cell source acquisition and transport, including travel and lodging of related donor for harvest procedure. **Rationale**: Obtaining the cell source is a necessary part of the transplant process. For allogeneic unrelated HCT, cost of procurement is dependent on donor location and type of cells selected for transplant. **Administrative Guidance**: Place search and procurement benefits in separate categories to ensure availability for each stage.
Cell Infusion or Transplant	**Recommendation:** Full coverage of HCT and subsequent therapeutic infusions for all medically necessary indications, including full coverage of all relevant hospital stays. **Rationale**: HCT indications are expanding rapidly and improving the lives of patients with otherwise fatal conditions. Limiting access to HCT as a treatment option may result in increased costs and poor patient outcomes, including death. **Administrative Guidance:** HCT and the associated services fit within the definition of Essential Health Benefits as defined by the Department of Health and Human Services and therefore should not be subject to an annual dollar limitation. For information on transplant indications, visit CIBMTR.org. Limitation of bed days or hospital days on an annual basis is counterproductive to treatment and may be life-threatening. Several inpatient visits are needed for treatment of primary disease, preparation for transplant and recovery. Length of stay varies by disease, condition, cell or graft source success and complications. Utilization of a standard transplant authorization form can streamline requests and reduce processing time. A standard form can be found at Payor.BeTheMatchClinical.org
Medications	**Recommendation**: Full coverage, without co-pay or co-insurance, of all necessary medications throughout the HCT process, including the post-transplant period with access to in-person pharmacies not just mail order pharmacies. **Rationale**: Access to medication is critical for success of HCT. Prohibitive co-payments or co-insurance may result in non-compliance, poor outcomes, graft failure and/or expensive hospitals readmissions due to infection or complications. **Administrative Guidance**: Off-label use of medications is common for the treatment of cancer care of all types, including hematologic malignancies and HCT. Have health plan case management team review list of prescribed medications and work with the patients Pharmacy Benefit Manager (PBM) to issue a test claim prior to discharge.
Clinical Trials	**Recommendation**: Full coverage of routine care in clinical trials appropriate to the patient's disease, treatment stage and clinical condition. **Rationale:** Limiting access to clinical trials slows improvements in standards of care. Paying for identical care outside of a clinical trial has identical cost without gaining future benefit. **Administrative Guidance:** As of 2014, the Affordable Care Act requires coverage of all routine costs associated with clinical trials that meet sponsorship or approval requirements.

The recommendations in this guide were developed by a stakeholder group convened by the National Marrow Donor Program®, including: transplant physicians, representatives from national health insurance companies and transplant networks, and administrators from hospitals with HCT programs.

NATIONAL MARROW DONOR PROGRAM®

BE THE MATCH®

Unrelated Donor: Search Costs

Every year, thousands of people of all ages are diagnosed with leukemia and other life-threatening diseases. Many of them will die unless they get a bone marrow or cord blood transplant from a matching donor. Seventy percent of people do not have a donor in their family and depend on the Be The Match Registry®, operated by the National Marrow Donor Program® (NMDP), to find a match to save their life.

Search process

When a patient requires a transplant from an unrelated donor, a physician can request a free **preliminary search** of the Be The Match Registry to determine if there are potential matches.

To verify that potential donors or cord blood units match the patient, NMDP transplant center physicians can initiate a **formal search** to request further testing. A formal search includes a one-time activation fee plus additional costs for outreach and lab tests of potential donors and/or cord blood units.

Search costs

Performed by	Donor search activity	Typical cost range	Description
NMDP	Preliminary search	No cost	Returns a snapshot of potential matched unrelated donors and umbilical cord blood units
NMDP	Formal search activation fee	$1,100-$2,500	One-time fee that covers the initiation of a patient's formal search profile
NMDP	Donor management	$5,000-15,000	Includes donor outreach, high-resolution HLA testing, health history screening, infectious disease testing and collection of samples for use by transplant centers
Transplant center	HLA typing	Determined by transplant center	Additional HLA typing of donor samples must be completed by transplant centers

Donor management costs include high-resolution Human Leukocyte Antigen (HLA) typing requests, adult donor infectious disease testing and shipment of donor blood samples to a transplant center. These costs, however, **do not cover HLA typing that must be completed at the patient's transplant center.** Each patient's donor search is unique, and depending on the difficulty of the search, a transplant center may need to perform HLA typing on several potential donors, incurring costs for each. These costs vary among transplant centers.

LEARN MORE > Payor.BeTheMatchClinical.org

For information on costs, payor-focused education programs, transplant outcomes data, CPT coding help and much more, visit Payor.BeTheMatchClinical.org or contact NMDPPayorPolicy@nmdp.org

EXAMPLE >
Search Process

This is for illustrative purposes only; each transplant situation is unique.

An adult patient is referred to a transplant center with a life-threatening disease, such as acute lymphoblastic leukemia. Because the patient does not have a sibling match, the transplant center physician requests a free **preliminary search** of the Be The Match Registry, which identifies several potential matched unrelated adult donors and cord blood units.

The transplant physician activates a **formal search** by requesting specific high-resolution typing on a small number of adult donors who have a high likelihood of matching, as well as HLA typing on a few partially matched cord blood units. The transplant center is charged a one-time **formal search activation fee** and typing costs for those donors willing and medically eligible to proceed to donation.

After receiving high-resolution typing results, the patient's physician requests a few select donors to have fresh blood samples drawn for infectious disease testing and additional HLA testing at the transplant center. The transplant center is charged a **donor management fee** for donor health screening, drawing and shipping fresh blood samples, and performing infectious disease testing.

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Transplant Benefits & Coverage

Blood and marrow transplant (BMT) has become a standard of care for many blood cancer and genetic diseases as well as a newer treatment option for others. For many patients, BMT represents the best or only option for a cure. Timely transplant has led to significantly improved outcomes, so patients who need a transplant also need appropriate coverage in place to ensure there are not delays to treatment. Learn about key aspects of transplant and the benefits that will support patients through the process.

For more information, please see our Recommended Benefit Plan Design (PDF).

- See our recommended transplant benefits featured in the NCCN and NBGH's "An Employer's Guide to Cancer Treatment & Prevention"

Steps in a Search for an Unrelated Donor

Only 30% of patients will have a sibling who matches and is able to donate. The other 70%, or approximately 10,000 people per year, need an unrelated donor to donate their healthy marrow or to use a previously donated umbilical cord blood unit. The Be The Match Registry® can be searched for those patients who do not have a related donor. The search process includes:

- **Preliminary Search**: When a patient requires a transplant from an unrelated donor, a physician can request a free preliminary search of our Be The Match Registry to determine if there are potential matches. This search returns a snapshot of potential matched unrelated donors and umbilical cord blood units (CBUs).
- **Formal Search**: To verify that potential donors or cord blood units match the patient, transplant center physicians in our network can initiate a formal search to request further testing of potential donors or CBUs listed on our registry. A formal search includes a one-time activation fee plus additional costs for outreach and lab tests of potential donors and/or CBUs.
- **Donor Management and HLA Typing**: Our donor centers contact potential donors, set up appointments, and perform high-resolution HLA testing, health history screening, infectious disease testing and collect samples for use by transplant centers. Costs vary because of the number of donors that need to be tested to find an actual match. To understand more about this process and the associated costs, please see our Search Costs document (PDF).
- **Cell Procurement/Infusion**: The cost of procuring unrelated donor cells varies greatly depending on the cell type and transplant protocol. These costs may be as low as $30,000 or

higher than $60,000 in cases where a patient requires two simultaneous infusions of cells, such as a double cord blood transplant.

Costs also vary based on the location of the donor or cord blood unit that is the best match for the patient. We work with a number of registries across the world to have access to international donors. Each registry sets its own price for donor products. Cord blood unit prices vary by cord blood bank, as each sets its own fees. To learn more about this process, please see our Procurement Costs document (PDF).

Key Benefits for Supporting the Transplant Process:

There are several components to transplant that require specialized benefit support. Providing these benefits will greatly assist in achieving the best possible outcome for the patient.

- **Donor Search and Cell Acquisition**: The process for identifying a donor and acquiring the cells used for BMT is substantially different than the process used in solid organ transplantation. Patients need full coverage for HLA typing of themselves, their potential related donors and the potential donors on the Be The Match registry. They also need coverage for the cell source that is identified based on their particular clinical situation—marrow, PBSC or cord blood.
- **Inpatient Stays and Clinic Visits**: Patients receiving an unrelated donor transplant may stay in the hospital up to 100 days after cell infusion. They will also need a number of follow-up clinic visits and many of these may need to be at the hospital where they received their transplant, due to the specialization and training of the clinical teams.
- **Medications**: Access to medications is critical for success of BMT. Prohibitive co-payments or co-insurance on medications may result in non-compliance, poor outcomes, graft failure and/or expensive hospital readmissions due to infection or complications.
- **Clinical Trials**: The remarkable improvement in outcomes of HCT has been made possible because of clinical trials. Many patients who receive an HCT will be asked to join a clinical trial. The trials used in HCT do not mean that the medication or treatment is unproven or never before tested. Often the trial will test two standard options to determine which yield better results. Results of clinical trials improve care for all patients. Identical care outside of a trial has identical cost without gaining future benefit from trial outcomes.
- **Travel/Lodging**: Patients may need to travel during the transplant process for a variety of reasons—access to an in-network transplant center, access to a center that specializes in their disease condition, and/or follow-up care post-transplant with their original treatment team. The typical travel and lodging allows for up to $10,000 in travel related costs and follows IRS specifications in how the benefit can be provided.

Our Websites

National Marrow Donor Program —
Entrusted to operate the C.W. Bill Young Cell Transplantation Program, including Be The Match Registry®.

Biology of Blood and Marrow Transplantation

journal homepage: www.bbmt.org

ASBMT American Society for Blood and Marrow Transplantation

Opinion

Optimal Benefits for Hematopoietic Stem Cell Transplantation: A Consensus Opinion

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A B S T R A C T

Variability in transplantation benefits may directly affect outcomes of individuals undergoing autologous or allogeneic hematopoietic stem cell transplantation procedures. The Financial Working Group of the National Marrow Donor Program–sponsored System Capacity Initiative addressed the issue of variable benefits and reviewed multiple transplantation benefit packages from both public and private payer organizations. On completion of the review, a consensus was obtained on defining a recipient benefit package that avoids major coverage gaps that could negatively influence patient outcomes. The recommendation was to encourage adoption of these benefits at a national level by payers, benefit brokers/consultants, and sales teams.

INTRODUCTION

Hematopoietic stem cell transplantation (HCT) remains the standard of care and often the only curative treatment option for a wide range of diseases, including high-risk and relapsed hematologic malignancies [1]. Currently, approximately 20,000 HCT procedures are performed in the United States each year [2–5]. HCT can be performed with either autologous (ie, the patient's own) or allogeneic (from a full or partially HLA-matched family member or unrelated donor) hematopoietic stem cells (HSC). The choice of the optimal HSC source is influenced by the nature of the underlying disorder, its responsiveness to chemotherapy, and its sensitivity to the immunologic effects mediated by an allogeneic donor graft. Medical considerations that may influence the decision to proceed to transplantation and the choice of HSC donor include disease stage and risk of relapse, patient age, and the presence of medical comorbidities. In addition, nonmedical reasons, including socioeconomic factors, such as the availability of a support network and access to financial resources, including payer availability, may influence the decision to perform HCT.

A recognized but understudied issue has been the impact of payer source on transplantation outcomes. In the United States, a multipayer system that includes state and federal governmental payers, as well as commercial ('third party') sources, exists. As the safety and efficacy of transplantation have improved over time for most diseases in which autologous and allogeneic HCT are used, transplantation has dramatically increased. Given the inevitable increases in costs associated with providing care for an increased number of transplantation patients, some payers have placed limitations on transplantation benefits, which may have unintended consequences for key clinical outcomes, including overall survival and quality of life. Studies have documented that HCT outcomes can be influenced by race and financial status, and analyses have suggested that the composition of a payer benefits package can positively or negatively affect outcomes [6]. As an example, it has been recognized that patients who are in need of allogeneic HCT often have benefit policies with inadequate "donor search" benefits—meaning coverage for the costs of finding and typing potential allogeneic donors. Clinical trial coverage varies by payer and may improve somewhat under the new requirements of the Affordable Care Act (ACA) implemented in 2014, but it is often a significant financial barrier, particularly in the case of emerging disease indications for HCT [7]. Finally, coverage for obtaining outpatient post-transplantation medications can be problematic for patients; substantial monthly expenses may be encountered because of high copays and coinsurance for specialized medications, with vast differences in coverage observed between individual self-funded

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† On behalf of the Financial Working Group of the National Marrow Donor Program System Capacity Initiative.

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private payer plans and in benefits offered by governmental payers (eg, Medicare and state Medicaid plans).

THE NATIONAL MARROW DONOR PROGRAM SYSTEM CAPACITY INITIATIVE FINANCIAL WORKING GROUP

In September 2009, the National Marrow Donor Program (NMDP) organized the System Capacity Initiative (SCI), a 3-year project to assess the current health care system's ability to accommodate the predicted growth in the number of patients who will need an HCT by 2020. The SCI initiative addressed, through the formation of individual working groups, a wide range of HCT-related issues, including workforce availability, care delivery systems, education, access, and reimbursement [8,9]. As part of this initiative, a Financial Working Group (FWG) was assembled to identify and address financial barriers to transplantation. The FWG members represented a cross-section of the transplantation community, including transplantation medical directors, representatives of leading commercial payers, including medical and program directors responsible for payment for complex medical services, transplantation center administrators, and transplantation-specific risk management and contracting organizations leaders.

The initial efforts of the FWG were focused on identifying the scope of its activities, and, ultimately, in defining areas which the multidisciplinary FWG could provide guidance to the transplantation and payer communities. Under the auspices of the US Health Resources and Services Administration, an initiative to define a modern list of diseases appropriately treated with HCT, and for which coverage should be provided, was already underway and continues at present; therefore, it was felt that the group should support and not duplicate its efforts. Endorsement was provided for the need to create a catalogue of individual state Medicaid benefits, and this effort was individually pursued by the health services research division of the NMDP [10]. Ultimately, the entire committee decided to focus on 4 major issues, with the recognition that the effort could be completed within the 36-month period and yield working products that reflected a consensus opinion of the members of the diverse group. These projects included the following: (1) the creation of consensus guidelines that would define the appropriate benefit package for the HCT recipient, (2) the development of tools to enhance the efficiency of the preauthorization process for private payers, (3) the creation of materials and tools to educate transplantation centers on the complexity of coding in reimbursement, and (4) the generation of a plan to communicate these consensus opinions and tools for the broader HCT community, including transplantation medical directors, center administrators, leadership within groups of public and commercial payers, and the greater health care purchaser industry involved in transplantation benefits formulation and administration, including plan managers, benefit consultants, and reinsurers.

METHODS

Process of Benefits Analysis and Development of a Consensus Benefits Package

An FWG subcommittee was formed to define the key elements of a consensus benefit package. The first step was the confirmation and ascertainment of the need for a clear set of recipient benefits for patients undergoing allogeneic and autologous HCT, based on available clinical and administrative best practices. This deliverable was identified as a priority effort because of the readily discernible, wide variation in benefits packages known to the subcommittee members. The group acquired, and reviewed in detail, information regarding individual benefit packages from a wide range of commercial payers and the available benefits provided by various state Medicaid agencies and Medicare coverage standards. There was a consensus that many governmental payers, particularly state Medicaid plans, provided limited and often inadequate HCT benefits, an observation that led to an independent NMDP policy team analysis, which confirmed this view [9]. The group also recognized that there has been extensive growth in the number of self-funded plans that, although often administered by major commercial payers, were the ultimate arbiters of benefits provided to their own employees. There was also recognition that HCT-associated benefits may not be entirely defined by the primary payer, but that reinsurer groups can also be responsible for transplantation and other complex services carved out of the primary benefits package. Specifically, there was a focused effort to examine both benefits provided by entities that provide reinsurance coverage to an employer's self-insured benefit plan (the circumstance where the reinsurer does not define benefits under the employer's plan but rather establishes which benefits are covered under the reinsurance coverage) and a second group of payer entities that provide insurance (not reinsurance) coverage for transplantation benefits that have truly been carved out of the medical benefit set. In this latter circumstance, the entity is providing fully insured (not self-insured) coverage for a defined set of transplantation services that has been carved out—ie, excluded—under the employer's self-insured benefit plan, thus protecting the employer from the financial risk associated with variability in delivery of transplantation services.

As a next step, the working group documented benefits that were universally included within multiple plans. The group then generated a process map required by the transplant recipient, recognizing the high variability of clinical course, based upon the type of transplantation that was to be undertaken. With these steps completed, the group assessed frequent incongruities between benefit plans and also identified common gaps in coverage. The potential clinical consequences of coverage gaps were then discussed and evaluated, with consideration of the costs associated with coverage and the potential unintended consequences (clinical and financial) of benefit limitations. The final steps of the process were to create a document defining a recommended set of insurance benefits derived from clear consensus of all stakeholders and of sufficiently high visibility to encourage near-universal adoption by all payers, benefit brokers/consultants, and account sales teams.

RESULTS

Recommended Benefits for HCT

Benefits described are those that the committee felt provided appropriate support to a patient and his/her care team to maximize the likelihood of achieving optimal HCT outcomes (Table 1). Coverage for HCT and all subsequent therapeutic interventions, and support for travel and lodging, as well as for outpatient care and caregiver requirements, should be provided for any patient with a medically necessary indication and adequate physiologic reserve such that acceptable long-term outcomes could be achieved. Transplantation indications are expanding rapidly and it is recognized that HCT may be either a curative option or life-extending procedure for many patients. Limiting or delaying access to transplantation may result in increased costs and poor patient outcomes, including death. Financial limits for reimbursement of HCT costs, either for the procedure or for medical costs over a patient's lifetime, should not have predetermined restrictive ceilings. Determination of the diagnostic indications for HCT procedures was not felt to be the purview of the subcommittee, but rather, deferred to national organizations or payer bodies performing evidence-based assessments of the value of HCT compared with alternate strategies that are continually evolving.

Donor Search

In the case of an allogeneic HCT, coverage should be provided for HLA typing of the patient and potential donors to identify the best possible "match" or best available cellular product. Related donors will primarily include fully HLA-matched siblings but may also be extended to other family members, while recognizing that less than fully HLA-matched donors are acceptable in selected situations. Unrelated donor HCT procedures have been increasing dramatically over the

Table 1
Benefit Design for Hematopoietic Cell Transplantation: Recommendations for Designing an Effective Health Insurance Benefit Set

Benefit Category	Recommendations
Allogeneic donor search process	Recommendation: Full coverage of tissue typing of patient, potential related donors, and unrelated donors through Be The Match or other approved registry. Rationale: Seventy percent of patients do not have a fully matched sibling donor. Limiting or excluding search coverage delays transplantation and can result in unnecessary and costly complications. Information about average costs and processes can be found at http://payor.bethematchclinical.org. Administrative guidance: Place search and procurement benefits in separate categories to ensure availability for each stage. Requiring proof of donor insurance policy denial for typing will unnecessarily delay the process; all policies prohibit coverage of costs when a member is acting as a donor. The Medicare claims processing manual indicates that donors should never be billed for transplantation costs.
Cell procurement or acquisition	Recommendation: Full coverage of cell source acquisition and transport, including travel and lodging of related donor, for harvest procedure. Rationale: Obtaining the cell source is a necessary part of the transplantation process. For allogeneic unrelated HCT, cost of procurement is dependent on donor location and type of cells selected for transplantation. Administrative guidance: Place search and procurement benefits in separate categories to ensure availability for each stage.
Cell infusion or transplantation; hospital length of stay	Recommendation: Full coverage of HCT and subsequent therapeutic infusions for all medically necessary indications, including full coverage of all relevant hospital stays. Rationale: Transplantation indications are expanding rapidly and improving the lives of patients with otherwise fatal conditions. Limiting access to HCT as a treatment option may result in increased costs and poor patient outcomes, including death. Administrative guidance: HCT and the associated services fit within the definition of Essential Health Benefits as defined by the Department of Health and Human Services and, therefore, should not be subject to an annual dollar limitation. For information on transplantation indications, please visit www.CIBMTR.org. Limitation of bed days or hospital days on an annual basis is counterproductive to treatment and may be life-threatening. Several inpatient visits are needed for treatment of primary disease, preparation for transplant and recovery. Length of stay varies by disease, condition, cell or graft source success and complications. Utilization of a standard transplantation authorization form can streamline requests and reduce processing time. A standard form can be found at www.payor.bethematchclinical.org
Travel and lodging	Recommendation: Full coverage of travel and lodging costs for member and caregiver(s) for the transplantation visit, in addition to necessary pre- and post-transplantation evaluations. Cover costs for additional caregiver travel, if patient is under 18 years of age. Rationale: Patient will likely have to travel to a transplantation center able to treat their condition and/or within their insurance network. Allogeneic HCT programs may require patient to stay near center for up to 100 days after transplantation. Limiting travel/lodging benefits may result in complications caused by delayed care and/or patient seeking care from nonspecialist care teams. Administrative guidance: Encourage member to use discounted housing options if available through the transplantation program. Adopt IRS reimbursement guidelines for taxable amounts allowed for health-related travel or allow flexible spending of plan-determined patient allocation. Patient will need to report to IRS on 1099 form. Consider use of reusable debit card.
Medications	Recommendation: Full coverage, without copay or coinsurance, of all necessary medications throughout the HCT process, including the post-transplantation period. Rationale: Access to medication is critical for success of HCT. Prohibitive copayments or coinsurance may result in noncompliance, poor outcomes, graft failure, and/or expensive hospitals readmissions due to infection or complications. Administrative guidance: Off-label use of medications is common for the treatment of cancer care of all types, including hematologic malignancies and HCT. Have health plan case management team review list of prescribed medications and work with the patients pharmacy benefit manager to issue a test claim before discharge.
Clinical trials	Recommendation: Full coverage of routine care in clinical trials appropriate to the patient's disease, treatment stage, and clinical condition. Rationale: Limiting access to clinical trials slows improvements in standards of care. Paying for identical care outside of a clinical trial has identical cost without potential of future benefit. Administrative guidance: As of 2014, the ACA requires coverage of all routine costs associated with clinical trials that meet sponsorship or approval requirements.

IRS indicates Internal Revenue Service.

past decade [3,4]. Molecular HLA typing of identified potential unrelated adult donors and/or cord blood units should be covered when facilitated through Be The Match or another payer-approved donor registry, such as the Anthony Nolan Registry or the Delete Blood Cancer Deutsche Knochenmarkspenderdatei gGmbH (Translation: German Bone Marrow Donor Center). Potential unrelated donors have preliminary typing results available through the Be The Match registry but need additional and more detailed confirmatory testing before selection of the best donor. Limiting or excluding coverage for donor typing can result in a suboptimal donor choice, which may lead to increased rates of complications associated with increased morbidity and mortality, including graft-versus-host disease and graft rejection. As donation timelines may vary between individual donors, limitation of search services may negatively affect transplantation timing, possibly increasing the risk of disease progression before HCT or treatment failure after transplantation. Increases in complication rates and the corresponding consequences of these complications may increase overall costs. Coverage should be provided for the medical evaluation of the donor as well as the requisite laboratory screening needed to identify potential transmissible hematologic, autoimmune, or infectious diseases. Administrative recommendations for payer consideration were to place search and procurement funding into a separate benefits compartment to ensure funds would be available.

Cell Acquisition and Procurement

Coverage recommendations for cell acquisition vary by transplant and donor type. Autologous HCT patients need full coverage for preparation/mobilization, collection, cryopreservation, and storage of cells. Clarification of the onset of autologous product mobilization and collection is needed, recognizing the different approaches (and associated costs) resulting from strategies that commonly include mobilization after the administration of cytotoxic chemotherapy followed by growth factors, compared with the use of growth factors alone for mobilization of peripheral blood stem cells. Allogeneic HCT recipients need full coverage for donor clearance, preparation, mobilization, and cell collection, transportation, and delivery costs. This includes costs associated with

unrelated donor products, which may include single or double umbilical cord blood products, bone marrow products collected by operative harvesting, or peripheral blood stem cells products collected by apheresis after administration of growth factors to healthy donors. In some circumstances, there may need to be allowances for variable practice, including need for cryopreservation, thawing, and preparation of HSC, including enrichment and/or depletion of graft subsets, depending on the situation and donor source. When a fully or partially HLA-matched related donor is utilized, coverage for donor travel to and lodging at the patient's transplantation center should be provided, when necessary, in addition to the actual procurement. Administrative recommendations for payer consideration were to place search and procurement funding into a separate benefits compartment to ensure funds would be available.

Cell Infusion ("Transplantation") Procedures

Full coverage of the actual cell infusion procedure should be provided. Financial support for management of the primary hospitalization and long-term medical complications should be planned. Administrative guidance recommendations include placing all transplantation benefits under general medical benefits spending and/or not to implement a separate transplantation-only benefit and spending limit. This recommendation has been further clarified by the ACA, as transplantation procedures are within the scope of the Essential Health Benefit set and cannot be restricted by qualified health plans. There has been the steady adoption of transplantation benefits to cover a variably defined episode of care (ie, preparation, infusion, and a number of recovery days, usually 100), rather than what is the tightly temporally defined procedure. There is an emerging understanding that the primary transplantation HSC infusion is distinct from subsequent infusion episodes (eg, performed to treat graft failure and/or relapse) and that consistent terminology regarding associated practices is needed. Recent efforts by professional societies and payers have led to the development of consensus statements [11], and the FWG expressed support for further efforts to develop and maintain consistency of terminology used by various stakeholders in the HCT community.

Travel and Lodging

Full coverage is recommended for travel and lodging costs for a patient and his/her caregiver(s) for transplantation candidacy evaluation, preparation, and the procedure itself, in addition to post-transplantation follow-up visits. In the case of a pediatric or adolescent/young adult patient, coverage for a second caregiver and/or allowance for alternating caregivers is often needed and should be covered. Patients may be required to stay within close range of a transplantation center for several months after HCT, with longer intervals (up to several months) typically required in the setting of allogeneic transplantation. Limiting travel and lodging benefits may create financial barriers for patients pursuing transplantation as a treatment option and reduces their ability to seek appropriate follow-up care with their primary transplantation team, which may lead to suboptimal management of complications and increased risk and cost of complications. Payers can promote the use of discounted housing options offered by transplantation centers, particularly when relocating patients to an identified center of excellence within the transplantation network. Payers may choose to either adopt Internal Revenue Service guidelines for these benefits or allow flexible spending of an allowed amount and later issuing an Internal Revenue Service form 1099 to the patient. Consideration has been recommended for providing reloadable debit cards and for extension of travel and lodging benefits to support daily expenditures, such as food and local travel.

Hospital Care/Length of Stay

There should not be a limit placed on the number of inpatient days covered for an HCT patient during the course of a calendar year or subsequent years, as arbitrary limits could result in suboptimal management of early or late transplantation complications. The hospital stay for the HCT conditioning, infusion, and recovery periods can vary based on a variety of factors that govern transplantation risk (eg, patient clinical status, disease, graft type) and also the variable incidence of complications even within defined risk groups. Patients may also face inpatient stays for control of their malignancy before the transplantation process and multiple readmissions after transplantation for treatment of complications. The practice of setting arbitrary limits on hospital days was considered counterproductive to optimal treatment and may increase the risk of adverse outcomes with ultimately increased cost.

Clinical Trials

Coverage of clinical trial participation should be provided for trials appropriate to the patient's disease, stage, and clinical condition. Routine costs associated with clinical trials that are federally approved or sponsored (eg, HCT trials supported by the National Heart Lung Blood Institute (NHLBI) and National Cancer Institutes (NCI), including multicenter or single center studies performed at NCI-designated cancer centers) are required of most health insurance policies as of January 1, 2014, under the provisions of the ACA. However, coverage for well-designed clinical trials that have not secured federal funding should also be considered when recommended by a patient's care team, particularly for emerging transplantation indications. Well-designed, statistically sound, single institution, scientifically innovative trials, such as the recently published studies of chimeric antigen receptor-T cells in relapsed acute lymphoid leukemia from the University of Pennsylvania Abramson Cancer Center have played an important role in furthering the HCT field [12]. Limiting patient access only to multicenter, well-designed, nationally supported clinical trials has the risk of slowing improvement in standards of care that otherwise would continue to evolve at a high rate, given the rapid pace of scientific and clinical developments relevant to HCT. Paying for identical care outside of a clinical trial has identical cost without the collective societal benefit gained via clinical trials. HCT is an area of medicine with a high proportion of patients treated on clinical trials because of the complexity of the treatment, the variety of diseases treated, and the rapid evolution of best practices, including those efforts spearheaded by research consortiums that include the NHLBI- and NCI-sponsored Blood and Marrow Transplant Clinical Trials Network [13,14].

Prescription Medication

The HCT process is dependent on prescription medications, often required for years, that include antimicrobials agents, for prophylaxis and therapy, and immunosuppressive medications critical to the safety and success of allogeneic transplantation. Coverage of all necessary medications, particularly post-transplantation medications, should be provided, ideally with waived coinsurance or copay responsibilities. There was strong consensus that cost-sharing provisions intended to limit

unnecessary medication costs may be more likely, in the HCT setting, to result in noncompliance, leading to significant complications, including higher rates of graft-versus-host disease and/or infections, both of which are important causes of morbidity and mortality after HCT. Thus, noncompliance related to the financial burden of coinsurance or copay costs may result in poor outcomes and, ultimately, in expensive hospital readmissions. Off-label use of medications is commonplace in cancer treatment protocols and in supportive care of HCT patients, supported by a strong evidence base for multiple off-label medications used in HCT patients. A review of patients' medications between all stakeholders is recommended before discharge, as is a test claim of the medications to identify cost and/or coverage problems. A test claim is the "dummy" submission of the prescription claim from the hospital to the payer, which results in detailed information as to any potential copays, formulary issues, and denied medications.

DISCUSSION

The management of the HCT recipient, whether the patient has undergone an autologous or allogeneic procedure, is a complex process requiring extensive medical evaluation, the complex delivery of ambulatory and inpatient services, and a need for ongoing diagnostic clinical and laboratory evaluations. All of these efforts must be performed with ongoing awareness and attention to the underlying disease and associated medical comorbidities, with contextual clinical decision-making considering a variety of socioeconomic factors, such as patient education, caregiver support, and access to health care systems; all of these factors ultimately influence individual patient outcomes. Not surprisingly, the total costs of HCT will be significant and may be accrued over an extended period of time [15,16]. Total HCT episode costs are likely to continue to rise because of expanded utilization of HCT and improved survival after transplantation. The increasing costs of HCT must be considered in the context of rising general costs for the diseases most often indicated for transplantation, as leukemia and lymphoma have already been identified by the NCI within the top 6 cancer disease categories that result in the greatest annual cancer expenditure [17]. To maximize the possibility of achieving optimal outcomes, the workforce must be intact [18] and the financial support and clinical infrastructure needed to provide care to individuals undergoing intensive cancer therapies must be assured. These goals motivated the establishment of the NMDP SCI and its subcommittees, including the FWG, which identified a high-priority need to define the key elements of an effective financial benefits package for the transplantation patient and to subsequently facilitate understanding and adoption of these recommendations.

This manuscript has described the details of the recommended transplantation recipient benefit package, outlining the importance of subcategories that need to be considered. Historically, there has been a tendency to fragment transplantation benefits packages, with independent allocations for individual elements of care (eg, search, transplantation medical benefits, and general medical care). This compartmentalization may contribute to disjointed and often suboptimal care of the HCT patient. Dramatic variations in payer benefits packages may also limit the ability of transplantation centers to practice consistent and evidenced-based care or develop clear patient medical pathways, resulting in a need to deviate from uniform care standards as a result of restraints imposed by divergent benefits packages. The effort of the FWG to define a transplant recipient benefit package is an important first step toward improving the consistency of care and an iterative process, wherein outcomes are optimized while minimizing the costs of care to the individual patient and to the health care system. We recognize that adopting any perceived expansion of benefits requires a detailed cost analysis of the total episode of care to determine if additional costs to the system have been incurred but ideally, an optimal benefit package could contribute to outcome improvement in diminished complications through additional supportive care. We also recognize that there already exists significant variation in inpatient costs among HCT transplantation centers, as recently documented by the analysis of Thao et al. [19]. We also anticipate that there will be ongoing analysis during the expected evolution of care delivery as a product of expansion of the transplantation-eligible patient population that will be the result of the ACA; the 2014 implementation of key provisions of the ACA impact access to HCT in numerous ways and a separate and specific analysis has recently been published by the NMDP health policy team [20].

We expect these guidelines to be reviewed by transplantation centers and payers, yielding further discussion and action, and immediate consequences of this consensus effort are already evident. Using the recipient benefit package as a model for care, a review of Oregon Health and Science University's institutional requests for transplantation benefits was performed and in a 4-month time line, 50% of the requests for preauthorization failed to meet SCI benefit guidelines (Maziarz, unpublished data: Oral presentation—NMDP Blood and Marrow Transplant: A Forum on Quality, Transparency, Cost, and Value [July 2013]). Preussler et al. have reviewed the US Medicaid programs and have demonstrated that no state provides coverage in all benefit categories [10]. Three states had adequate benefits for 4 of the categories; 21 states had adequate coverage for 3 categories; 15 states had adequate coverage for only 2 of the categories, and 8 states, including 2 of the most populous states of the country, met the proposed benefits in only 1 transplantation benefit category. These data suggest that education and advocacy will be necessary to ensure improvement of benefits packages at the state level.

On a more positive note, as a result of the generation of the SCI recommendation for covered transplantation benefits, the National Comprehensive Cancer Network and the National Business Group on Health have integrated these benefit recommendations into their Employer's Guide to Cancer Treatment and Prevention [21]. The National Business Group on Health/National Comprehensive Cancer Network series provides reference tools specific to cancer care and treatment for employers who are purchasing health care benefits. They recommend that coverage include pre-transplantation, transplantation, and post-transplantation care recommended by the transplantation center and that the benefit plan also include donor search and typing costs including: "full cost of biological sibling typing; full cost of unrelated donor search, including typing and testing of potential donors, through the NMDP or other approved registry; full cost of related donor procurement, including travel and lodging of the selected related donor for the donation process; and full cost of donor cell product procurement for the unrelated donor" [21]. Ongoing outreach activities are planned, through the NMDP and affiliated organizations, to extend education about and adoption of these consensus recommendations.

CONCLUSION

HCT is an important but complex treatment modality and continues to be utilized in an expanding fashion because of improved safety and efficacy for a broad range of indications. Although expensive, HCT has also been demonstrated to be cost effective for many indications, and it is often the treatment modality most likely to be curative or extend life in transplantation candidates. For underinsured or uninsured transplantation patients, facing the complex process of care with limited or no health insurance benefits is daunting and is very likely to undermine the likelihood of success. Because the major component of payer cost is for the transplantation procedure and hospitalization, attempts to control costs for ancillary processes or procedures, supportive care of the patient, or medications may paradoxically increase care because of an unintended increased risk of complications. It is the hope of the working group that all patients undergoing HCT will be able to concentrate on their compliance, recovery, healing, and quality of life rather than the long-term financial implications of their treatment.

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APPENDIX A

Request Form for Board of Trustee Consideration of a Change to SHP Benefits

This form is to be used by individuals or groups that would like to propose new benefits coverage or request changes to benefits already covered by the State Health Plan. Please read the Procedure – Requests for Benefits Changes, SHP-PRO-7001-SHPfor more information regarding these types of requests.

Please submit completed forms by email to SHP.Board@nctreasurer.com or mail to NCState Health Plan Board of Trustees, 4901 Glenwood Avenue, Suite 300, Raleigh, NC 27612-3638.

Name of Requestor: **North Carolina Association of Acupuncture and Oriental Medicine**

Contact Information (*phone, email, mailing address):*

Christina Daerr Reid, LAc
President of North Carolina Association of Acupuncture and Oriental Medicine
625 Essex Forest Drive
Cary, NC 27518
(910)547-8748
president@ncaaom.org

Requested Change in Benefits Coverage:
The inclusion of acupuncture as a covered benefit for state employees.

Reason for Request: **Scientific studies have shown that acupuncture is effective for a variety of ailments, from treating osteoarthritis and nausea to pain relief and addiction at a cost reduction in comparison to other treatment plans. State employees have requested the inclusion of acupuncture.**

Proposed Effective Date of Change: **January 1, 2016**

Supporting Documentation (*Please provide documents to support your request; examples include research or studies regarding medical services, treatment or procedures, fiscal impact analyses if available, or petitions from members.*):
In addition to Appendix A, we are providing the Board of Trustees with two studies illustrating outcome and cost effectiveness.

Would you like to speak with the Board of Trustees about this issue at a Board of Trustees meeting? **We respectfully request the opportunity to present before the Board of Trustees, a presentation highlighting the research and fiscal analysis to support the addition of acupuncture into the state health plan.**

The Board of Trustees reviews select requests annually at a regularly scheduled Board of Trustee meeting. For calendar year 2013, requests will be reviewed at the November meeting. For calendar year 2014, requests will be reviewed at the July meeting. Review of requests in no way obligates the State Treasurer to make changes to benefits.

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Comparison of Health Care Expenditures Among Insured Users and Nonusers of Complementary and Alternative Medicine in Washington State: A Cost Minimization Analysis

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Abstract

Objectives: The purpose of this analysis was to compare health care expenditures between insured patients with back pain, fibromyalgia syndrome, or menopause symptoms who used complementary and alternative medical (CAM) providers for some of their care to a matched group of patients who did not use any CAM care. Insurance coverage was equivalent for both conventional and CAM providers.
Design: Insurance claims data for 2000–2003 from Washington State, which mandates coverage of CAM providers, were analyzed. CAM-using patients were matched to CAM-nonusing patients based on age group, gender, index medical condition, overall disease burden, and prior-year expenditures.
Results: Both unadjusted tests and linear regression models indicated that CAM users had lower average expenditures than nonusers. (Unadjusted: \$3,797 versus \$4,153, $p = 0.0001$; β from linear regression -\$367 for CAM users.) CAM users had higher outpatient expenditures that which were offset by lower inpatient and imaging expenditures. The largest difference was seen in the patients with the heaviest disease burdens among whom CAM users averaged \$1,420 less than nonusers, $p < 0.0001$, which more than offset slightly higher average expenditures of \$158 among CAM users with lower disease burdens.
Conclusions: This analysis indicates that among insured patients with back pain, fibromyalgia, and menopause symptoms, after minimizing selection bias by matching patients who use CAM providers to those who do not, those who use CAM will have lower insurance expenditures than those who do not use CAM.

Introduction

THE USE OF COMPLEMENTARY AND ALTERNATIVE medicine (CAM) has grown in recent decades,[1,2] and as a result insurance coverage for various types of CAM providers has become more prevalent.[1,3–5] But due to concern over ever-increasing health care costs, increasing emphasis is being given to cost-effectiveness of care. Patients desire choices in sources of health care, but if CAM providers are to be added to insurance coverage, their care must be cost effective.

One researcher noted that CAM therapies may be good candidates not only for cost-effective care but even cost savings, because "they avoid high technology, offer inexpensive remedies, and harness the power of *vis medicatrix naturae* (the body's natural ability to heal itself)"[6]. However, several difficulties have hindered the assessment of CAM's cost effectiveness. One of the biggest challenges in evaluating the effect of CAM use on health care costs is the selection bias inherent in patients' self-selection into CAM using and non-CAM using groups.[7] Researchers have consistently reported that CAM users have poorer health status, more visits to conventional providers, and/or higher rates of hospitalization than nonusers.[8–14] Thus, it has been difficult to find or create comparable groups of CAM users and nonusers for which costs can be compared.

In the early 1990s, a Swiss group conducted a randomized clinical trial offering free insurance coverage of CAM providers to half of a group of insured individuals. They

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reported that covering CAM care did not lead to an increase in costs for the insurance company because CAM utilization comprised only a tiny percentage of overall expenditures.[15] Given the increase in CAM use since the early 1990s in the United States,[12] the cost of CAM coverage today might be larger than that found in the Swiss study. However, data from Washington State, which mandates private insurance coverage of all licensed CAM providers,[16] found a similar tiny percentage of expenditures devoted to CAM care based on data from 2002.[17] The Washington State data reflect self-selection of patients into CAM-using and nonusing groups and thus may reflect a more "real-world" experience for insurance companies than the Swiss randomized study.

Another difficulty in performing economic analyses of CAM use occurs because many CAM providers are not covered by insurance, and patients pay for their services out of pocket. As a result, data on CAM utilization and expenditures are not available in administrative databases and must be collected through primary data collection,[6] which may be subject to recall bias and response bias. Washington State provides a unique environment in which to perform an economic analysis of CAM use because of the state-mandated insurance coverage referenced above. As a result, administrative claims data from Washington State include data on CAM utilization and expenditure that are consistent with data for conventional care.

A final difficulty in performing a cost–benefit evaluation of CAM involves measuring outcomes of care. Data on outcomes of care are not available in the administrative claims databases often used to provide data on expenditures. With CAM care, a further difficulty lies in how to quantify what Hollinghurst refers to as "the wider benefits of CAM," some of which may appear over long periods of time or be based more on a patient's sense of well-being than a measurable clinical outcome.[7,18] To avoid these problems in measuring outcomes, this analysis takes a cost-minimization approach,[6] analyzing which of two approaches to care is associated with lower overall expenditures, assuming comparable health outcomes between the two approaches.

The purpose of this article is to compare insurance expenditures for matched groups of CAM users and nonusers with selected health conditions, to evaluate whether use of CAM for some care is associated with higher or lower overall health care expenditures.

Materials and Methods

Population

This research was approved by the institutional review boards of the University of Washington and Boise State University. The study sample was constructed using 2000–2003 enrollment and claims data from two large insurance companies in Washington State that offer a variety of product types. The analysis was restricted to insured individuals covered by the law requiring coverage of CAM providers, which excluded enrollees funded through Medicare, Medicaid, or other state or federal programs. The data acquisition process, data cleaning, and the creation of analytic variables have been previously described.[19] The analyses presented here were limited to adults aged 18–64 who had at least 2 continuous years of coverage and at least one visit that contained a diagnosis for one of the index conditions defined below.

Index conditions. Three health conditions were chosen for study: back pain, fibromyalgia syndrome (FMS), and menopause symptoms. These index conditions were selected because a substantial proportion of associated patients use CAM for at least part of their care.[17,20,21] FMS was defined as at least one visit containing ICD-9 code 729.1. Low back pain and menopause symptoms were defined using the Johns Hopkins Adjusted Clinical Group (ACG) software, Version 8,[22] which groups ICD-9 codes per visit into expanded diagnosis clusters (EDC). Low back pain was defined as EDC MUS14 (Low Back Pain) and menopause symptoms was defined as EDC FRE11 (Menopausal Symptoms).

Time frame. Two (2) time periods of interest were created. The "study year" for each patient started on the day of the first visit for an index condition and continued for 365 days; and the "prior year" for each patient was defined as the 365 days preceding the first visit for the index condition. All data were derived from calendar years 2000–2003.

Patients included in the analysis had at least one provider visit containing an ICD-9 code/EDC for an index condition during the study year and no visits containing an ICD-9 code/EDC for the index condition during the prior year.

Provider types. CAM providers were defined as chiropractors, licensed massage therapists, acupuncturists, and naturopathic physicians. Conventional providers were defined as physicians (including osteopaths and specialists), advanced registered nurse practitioners, and physician assistants.

Dependent variables. Dependent variables were total allowed expenditures in the study year, outpatient expenditures, expenditures related to the index condition, and expenditures related to imaging procedures (back pain patients only). Data for each visit included the dollar amount the insurance company allowed for that visit. These amounts were totaled over the study year to create total allowed expenditures. For some analyses, these totals are broken out into allowed expenditures for CAM visits versus allowed expenditures for conventional visits. Imaging expenditures were divided into expenditures for plain radiographs and expenditures for all other types of imaging (e.g., magnetic resonance imaging [MRI], computed tomography). Imaging expenditures were further divided into those that occurred within 28 days of the initial diagnosis (called "early" imaging) and those that occurred more than 28 days after initial diagnosis. This division was based on the Healthcare Effectiveness Data and Information Set recommendation that no imaging should be performed within the first 28 days after an initial diagnosis of back pain.[23]

Independent variables. Age, gender, and zip code were included in the claims information along with ICD-9 diagnosis codes, dates and types of visits, and providers seen. County population was calculated based on 2000 census data and then categorized as <100,000; 100,000–400,000; and >400,000.

CAM users were defined as patients with at least one visit to a CAM provider for the index condition during the study year. Most also had at least one visit to a conventional provider for the index condition. CAM nonusers were those with no visits to a CAM provider for any reason during the study year and at least one visit to a conventional provider for the index condition during the study year.

Overall disease burden for each patient was constructed using the Resource Utilization Band (RUB) index created by the Johns Hopkins ACG software described above. RUBs estimate the overall disease burden and expected resource use for each individual, and are created by grouping individuals with similar levels of expected resource use based on the ACG index. Lower RUBs included individuals with less expected resource use and higher RUBs included those with greater expected resource use. Throughout the Results and Tables, the term "Low disease burden" refers to patients in RUBs 1 and 2; "Moderate disease burden" refers to patients in RUB 3; and "High disease burden" refers to patients in RUBs 4 and 5. For the regression analysis, disease burden was dichotomized into high versus moderate or low.

Matching. Because patients were not randomly assigned to use CAM but rather self-selected into CAM users and nonusers, we used a matching process to create groups that were as comparable as possible, using a frequency matching process. That is, each CAM user was placed into a stratum based on index condition, gender, 10-year age group, total allowed expenditures during the prior year (matched within $1,000 up to $9,999; all expenditures $10,000 or above were grouped), and disease burden categorized as high, medium, or low during the study year. The number of CAM users in each stratum was determined and half that number of CAM nonusers in each stratum was randomly identified, resulting in a 2:1 match. The 2:1 matching process was necessary because there were too few CAM nonusers in many strata to create a 1:1 match. There were 1330 potential strata, of which 770 contained at least one CAM user. In 256 strata there were an odd number of CAM users, creating the need for a de facto 3:1 match for these individuals. In addition, there were 125 CAM users who could not be matched due to too few controls in the stratum. All CAM users were included in the analysis, including the total of 381 (1.4%) described above who could not be placed in a 2:1 match. Characteristics of unmatched CAM users are described in the Results section.

Statistical analysis. Independent samples t tests were used for unadjusted comparisons of expenditures (total, outpatient, and expenditures related to index condition) between CAM users and nonusers, also to compare mean age. Chi-square tests were used to compare distributions of gender, disease burden, county population, and insurance companies between CAM users and nonusers.

Linear regression analysis was used to perform adjusted comparisons of total expenditures between CAM users and nonusers after adjustment for age, gender, disease burden, county population, and insurance company. Disease burden was dichotomized as high disease burden versus low or moderate disease burden, and an interaction term between CAM use status and disease burden was included in the model. Beta estimates for the interaction terms were calculated using the lincom function in Stata (Stata Corp., College Station, TX).[24] Models were constructed for all patients combined and then separately for those with each index condition.

Although expenditure data are highly skewed, leading to a violation of the requirement for constant variance and for normally distributed residuals from the model, the large sample size available here ensures that estimates will be accurate, based on the Central Limit Theorem (CLT).[25] However, it was not apparent whether the groups with FMS ($n = 5508$) or menopause ($n = 6566$) were large enough for the CLT to apply for the two models created from these smaller samples. Two (2) simulation analyses were performed to determine this, one analysis for the FMS group and the other for the menopause group. In each case, 1000 bootstrap samples were created from the original sample and regression analyses were performed. If the CLT is applicable, 95% of the β estimates from these 1000 models should fall in the 95% confidence interval based on the entire group. Results of the analysis showed that for the FMS group, 97.2% of the β estimates fell into the 95% confidence interval, and for the menopause group, 96.8% of the β estimates fell into the 95% confidence interval. Based on these results, we were confident that the linear regression models would give us accurate estimates in spite of the skewed nature of the dependent variable. To ensure accurate inference, "robust" standard errors were used.[26] Stata version 10 was used for all analyses.[27]

Results

A total of 26,466 CAM users were identified for this analysis: 18,343 with back pain, 3722 with FMS, and 4401 with menopause. These were matched to 13,025 CAM nonusers on a 2:1 basis. There were 381 (1.4%) CAM users who were not matched in this process; 125 due to having no matching controls available and the remaining 256 due to having an odd number of CAM users in some strata. All CAM users were included in the analysis. Those who were unmatched were younger (mean 42.4 versus 45.2 years, $p < 0.0001$); had higher average total expenditures in the study year ($5,902 versus $3,766, $p < 0.0001$), and had heavier disease burdens in the study year (46% in highest category versus 33% among matched CAM users, $p < 0.0001$). To the extent the inclusion of these unmatched CAM users may lead to bias, it will make CAM users look more expensive than the matched controls. However, because the unmatched CAM users are only 1.4% of all CAM users, any bias will be small. For example, as stated above, the mean total expenditure was $3766 for matched CAM users. When the 381 unmatched CAM users were included, mean expenditure for all CAM users was $3,797.

Table 1 displays the comparison of the CAM users and nonusers. The groups did not differ on average age, average allowed expenditures in the prior year, percent female, or disease burden in the study year; that is, as expected, users and nonusers did not differ on any of the matching criteria. CAM users and nonusers were not matched on county population or insurance company, and CAM users were less likely to live in urban counties than nonusers, also more likely to be from insurance company B.

Table 2 displays the results of unadjusted t-tests which showed that CAM users had lower overall average

TABLE 1. COMPARISON OF COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) USERS AND NONUSERS[a] MATCHED ON AGE GROUP, GENDER, ALLOWED EXPENDITURES IN PRIOR YEAR, AND DISEASE BURDEN IN STUDY YEAR

	CAM users (n = *26,466*)	*CAM nonusers* (n = *13,025*)	p-*value*
Average age (SD)	45.2 (10.5)	45.4 (10.6)	0.14
Average allowed expenditures in prior year (SD)	$2,494 (6351)	$2,454 (6114)	0.55
Percent female	66.6%	66.7%	0.80
Disease burden in study year			
Low	8.3%	8.1%	0.72
Moderate	58.3	58.7	
High	33.4	33.2	
County population			
<100,000	11.9	8.4	<0.001
100,000–400,000	15.2	11.0	
>400,000	72.9	80.6	
Insurance company			
A	90.8	92.6	<0.001
B	9.2	7.4	

[a]CAM users, those with at least one visit to a CAM provider related to index condition during study year; nonusers, no visit to a CAM provider for any reason during study year.
SD, standard deviation.

expenditures than nonusers in the study year ($3,797 versus $4,153, $p = 0.0001$). The distribution of expenditures for outpatient, inpatient, and other expenditures differed between the two groups; CAM users had higher average outpatient expenditures ($1,848 versus $1,502, $p < 0.0001$) but lower inpatient expenses and lower expenses for other types of claims not linked to a specific provider visit such as imaging and lab claims (Fig. 1). Among CAM users, expenditures for conventional outpatient care were lower than among CAM nonusers ($1,219 versus $1,502, $p < 0.0001$), but this was offset by CAM expenditures, which averaged $630 per user.

TABLE 2. COMPARISON OF EXPENDITURES BETWEEN COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) USERS AND NONUSERS IN STUDY YEAR

	CAM users (n = *26,466*)	*CAM nonusers* (n = *13,025*)	p *value*
Average allowed expenditures in study year:	Mean (SD)	Mean (SD)	
Total	$3,797 (7623)	$4,153 (9505)	0.0001
Outpatient: Total	$1,848 (2370)	$1,502 (3027)	<0.0001
Conventional	$1,219 (2214)	$1,502 (3027)	<0.0001
CAM	$630 (746)	0	
Total related to index condition	$588 (1280)	$554 (1947)	0.04
Outpatient related to index condition	445 (594)	231 (438)	<0.0001

SD, standard deviation.

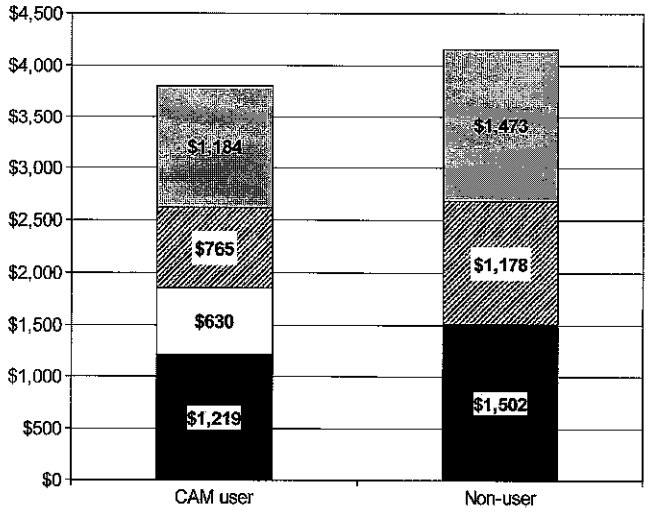

FIG. 1. Average annual allowed expenditures by complementary and alternative medicine (CAM) use status. Solid black, outpatient expenditures from conventional providers; solid white, outpatient expenditures from CAM providers; gray stripe, inpatient expenditures; solid gray, other expenditures not related to a provider visit, such as imaging and lab work.

When analyses were restricted to visits related to the index condition, total average expenditures were slightly higher among CAM users ($588 versus $554, $p = 0.04$), while average outpatient expenditures related to the index condition were much higher among CAM users ($445 versus $231, $p < 0.0001$) (Table 2). The expenditure patterns were similar within each condition (Table 3).

The linear regression analysis revealed a significant interaction between CAM use and disease burden. Among those in the low or moderate disease burden category, CAM users were predicted to have mean total expenditures $160 higher than nonusers. However, among those with high disease burden, predicted mean expenditures for CAM users were $1,421 lower than for nonusers (β: $6,726 for nonusers compared to $5,305 for CAM users, $p < 0.001$) (Table 4). When a model was fit excluding the interaction term, the β coefficient for CAM use was -$367 (standard error = $90, $p < 0.001$), confirming that overall, after adjustment, CAM users as a group have lower average total expenditures than nonusers. Similar results were seen in regression models restricted to each index condition.

The next set of analysis was aimed at identifying where the differences in expenditures between CAM users and nonusers occurred. Expenditures were analyzed by gender, and results showed that among males, CAM users had significantly lower expenditures than nonusers ($2,863 versus $3,634, $p < 0.0001$), while among females average expenditures did not differ significantly between CAM users and nonusers ($4,266 versus $4,412, $p = 0.19$). CAM users were less likely to be hospitalized (5.2% versus 7.5%, $p < 0.001$), and among those with menopause symptoms, CAM users were less likely to get a hysterectomy within 1 year of diagnosis (1.3% versus 2.9%, $p < 0.001$). Next we looked at the contribution of imaging to expenditures among back pain patients. CAM users were more likely than nonusers to have some type of imaging done (42.6% versus 38.3%, $p < 0.001$) and were also more likely to

TABLE 3. EXPENDITURES BY DISEASE CONDITION AND CAM USE STATUS

	Back pain		*FMS*		*Menopause*	
	User	*Nonuser*	*User*	*Nonuser*	*User*	*Nonuser*
N	18,343	9074	3722	1786	4401	2165
Mean allowed expenditures in study year						
Total	$3,410***	$3,739	$4,830*	$5,449	$4,535	$4,818
Outpatient	$1,637***	$1,312	$2,374***	$1,840	$2,285**	$2,019
Total related to index condition	$677	$660	$554***	$412	$249**	$223
Outpatient related to index condition	$511***	$259	$407***	$170	$207**	$166

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.
FMS, fibromyalgia syndrome.

have imaging done "early" (within 28 days of diagnosis): 12.5% versus 9.8%, $p < 0.001$. However, overall expenditures related to imaging were higher among nonusers, averaging (standard deviation) $197 ($485) compared to $140 ($388) among CAM users ($p < 0.0001$). This apparently contradictory finding is explained in that CAM users are more likely than nonusers to have plain radiographs (39% versus 28%, $p < 0.001$), and CAM users are less likely to have the other, more expensive types of imaging such as MRIs (11.4% versus 19.4%, $p < 0.001$).

Because CAM users were more likely to be covered by Company B and less likely to live in urban counties than nonusers, analyses were then performed to ensure that the differences in imaging were not due to differences in coverage between companies or differences in access to imaging between rural and urban residents. There was no significant difference in the percentage of back pain patients from Company A versus Company B who had MRI or other "high tech" imaging (all imaging other than plain x-ray). Rates were 14.0% for Company A and 14.7% for Company B ($p = 0.35$). Looking at the issue of access to high-tech imaging in rural areas, Table 5 shows that use of high-tech imaging was substantially lower for CAM users than nonusers for all three categories of county size. Furthermore, for nonusers, rates of high-tech imaging were very similar in the smallest counties (18%) and most urban counties (19%), indicating that lack of access in more rural areas does not explain the difference between CAM users and nonusers.

Discussion

The results of this analysis indicated that among patients with back pain, FMS, or menopause symptoms, those who used CAM providers for at least part of their care had slightly lower overall average expenditures than matched patients who saw conventional providers exclusively. The largest difference was seen among the patients with the heaviest disease burden, who tend to be the most expensive patients. Among patients with the lightest disease burden, CAM users tended to be slightly more expensive than nonusers. The majority of patients fall into the low and moderate disease categories, so this is not an inconsequential finding. However, the size of the cost saving among those with heavy disease burdens more than compensated for this; both the unadjusted results and the regression model omitting the interaction term showed that overall, CAM users had lower mean expenditures than nonusers. In fact, given the expected $356 lower expenditure for each CAM user, we

TABLE 4. RESULTS OF LINEAR REGRESSION MODEL[a]

	All conditions (n = 39,491)		*Back pain (n = 27,417)*		*FMS (n = 5508)*		*Menopause (n = 6566)*	
	β	*SE*	*β*	*SE*	*β*	*SE*	*β*	*SE*
Interaction of CAM use and disease burden:								
Low disease burden, CAM nonuser	Reference category							
Low disease burden, CAM user	$160***	$37	$93*	$41	$392***	$114	$322**	$108
High disease burden, CAM nonuser	$6,726***	$230	$6526***	$267	$7,973***	$747	$6468***	$476
High disease burden, CAM user	$5305***	$129	$5,196***	$164	$5,849***	$302	$5,335***	$287
Other covariates in the model:								
Age	$28***	$4	$31***	$4	$11	$17	$22	$19
Sex	$478***	$88	$452***	$87	$615	$333	–	–
County pop 100k–400k[b]	$166	$150	$267	$168	$-98	$469	$-45	$408
County pop >400k[b]	$239*	$121	$294*	$127	$96	$418	$127	$349
Insurance co.	$716***	$167	$771***	$204	$1,068*	$530	$416	$337
Constant	$-1,223	$280	$-1,362	$312	$-651	$1,001	$433	$952

[a]Outcome = total allowed expenditures in study year.
[b]Compared to counties with population <100k.
*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.
CAM, complementary and alternative medicine; FMS, fibromyalgia syndrome; SE, standard error.

TABLE 5. PERCENT OF BACK PAIN PATIENTS RECEIVING MAGNETIC RESONANCE IMAGING OR OTHER "HIGH-TECH" IMAGING BY COUNTY POPULATION AMONG COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) USERS AND NONUSERS

County population	*CAM nonusers*	*CAM users*	*Total*
<100k	18%	9%	11%
100–400k	21	10	13
>400k	19	12	15
Total	19	11	14

would expect an overall $9.4 million lower expenditure in a group of 26,466 CAM patients with these medical conditions compared to a similar group of CAM nonusers of equal size. CAM users actually had higher outpatient expenditures and more outpatient visits than nonusers, but this was offset by lower inpatient and other expenditures (such as high-tech imaging) among CAM users.

Both Nelson et al.[28] and Legorreta[29] et al. compared insured back pain patients with chiropractic insurance coverage to those without chiropractic insurance coverage and found that those with chiropractic coverage had lower average back pain episode-related costs as well as lower rates of both MR and radiographic imaging. Our findings extend these analyses in finding that among those with chiropractic insurance coverage, those who actually use this benefit have lower costs than those who do not. Our findings also confirm the findings of Sarnat[30] that use of CAM-oriented primary care providers was associated with lower costs than conventional primary care providers.

This analysis has several limitations. First, although CAM users and nonusers were matched as closely as possible, the results may reflect differences between the groups that were unaccounted for in the matching process. Demographic information available in claims data is quite limited and does not include potentially important factors such as income, education, or race. Earlier regression analyses with these data used zip code–level income, education, and race to attempt to adjust for these factors, but none were significant. This likely indicates that the zip code–level aggregation was not sensitive enough to model the effects of these variables in this instance (unpublished data). Due to the correlation between health status and income, matching by disease burden provided limited matching on income.

A second limitation is that claims data are collected primarily for billing reasons and as such may not reflect all diagnosis codes with ideal accuracy. Third, cost minimization assumes that health outcomes are equivalent between groups. We did not have appropriate data available to test this assumption. Finally, we do not know how CAM-using patients would have behaved if insurance coverage was not available for these visits; if they had substituted conventional care in place of CAM care, costs to the insurance company would likely have been higher, while if they had paid out-of-pocket for CAM care, costs to the insurance company would have been lower.

Conclusions

The conclusion of this analysis is that in a large group of insured individuals, patients who use CAM providers for some of their care have lower expenditures as a group than a matched group of patients who do not use CAM, and the difference in expenditures is related in large part to less inpatient care and less use of high-tech imaging.

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Disclosure Statement

No competing financial interests exist.

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Acupuncture for chronic pain: individual patient data meta-analysis

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Abstract

Background—Although acupuncture is widely used for chronic pain, there remains considerable controversy as to its value. We aimed to determine the effect size of acupuncture for four chronic pain conditions: back and neck pain, osteoarthritis, chronic headache, and shoulder pain.

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Ethics statement
An ethics statement was not required for this work.

Conflicts of Interest
The authors declare that they have no competing interests.

Authors' contributions
The study was conceived by AV, GL, CW, and KL. AV was responsible for the overall study design with input from AC for the statistical analysis; AM for the systematic review; GL and HM with respect to acupuncture analyses; NV, CW, NF, KS and KL with respect to clinical trial methodology and meta-analysis. Statistical analyses were conducted by AV, AC and AM. The first draft of the manuscript was written by AV and AM. All authors gave comments on early drafts and approved the final version of the manuscript. AV had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Methods—We conducted a systematic review to identify randomized trials of acupuncture for chronic pain where allocation concealment was determined unambiguously to be adequate. Individual patient data meta-analyses were conducted using data from 29 of 31 eligible trials, with a total of 17,922 patients analyzed.

Results—In the primary analysis including all eligible trials, acupuncture was superior to both sham and no acupuncture control for each pain condition (all $p<0.001$). After exclusion of an outlying set of trials that strongly favored acupuncture, the effect sizes were similar across pain conditions. Patients receiving acupuncture had less pain, with scores 0.23 (95% C.I. 0.13, 0.33), 0.16 (95% C.I. 0.07, 0.25) and 0.15 (95% C.I. 0.07, 0.24) standard deviations lower than sham controls for back and neck pain, osteoarthritis, and chronic headache respectively; the effect sizes in comparison to no acupuncture controls were 0.55 (95% C.I. 0.51, 0.58), 0.57 (95% C.I. 0.50, 0.64) and 0.42 (95% C.I. 0.37, 0.46). These results were robust to a variety of sensitivity analyses, including those related to publication bias.

Conclusions—Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo. However, these differences are relatively modest, suggesting that factors in addition to the specific effects of needling are important contributors to the therapeutic effects of acupuncture.

Introduction

Acupuncture is the insertion and stimulation of needles at specific points on the body to facilitate recovery of health. Although initially developed as part of traditional Chinese medicine, some contemporary acupuncturists, particularly those with medical qualifications, understand acupuncture in physiologic terms, without reference to pre-modern concepts[1].

An estimated 3 million American adults receive acupuncture treatment each year[2], and chronic pain is the most common presentation[3]. Acupuncture is known to have physiologic effects relevant to analgesia[4, 5], but there is no accepted mechanism by which it could have persisting effects on chronic pain. This lack of biological plausibility, and its provenance in theories lying outside of biomedicine, makes acupuncture a highly controversial therapy.

A large number of randomized trials of acupuncture for chronic pain have been conducted. Most have been of low methodologic quality and, accordingly, meta-analyses based on these trials are of questionable interpretability and value[6]. Here we present an individual patient data meta-analysis of randomized trials of acupuncture for chronic pain, where only high quality trials were eligible for inclusion. Individual patient data meta-analysis is superior to the use of summary data in meta-analysis as it enhances data quality, enables different forms of outcome to be combined, and allows use of statistical techniques of increased precision.

Methods

The full protocol of the meta-analysis has been published.[6] In brief, the study was conducted in three phases: identification of eligible trials; collection, checking and harmonization of raw data; individual patient data meta-analysis.

Data Sources and Searches

To identify papers, we searched MEDLINE, the Cochrane Collaboration Central Register of Controlled Trials and the citation lists of systematic reviews (full search strategy in Appendix). There were no language restrictions. The initial search, current to November 2008, was used to identify studies for the individual patient data meta-analysis; a second search was conducted in December 2010 for summary data to use in a sensitivity analysis.

Study Selection

Two reviewers applied inclusion criteria for potentially eligible papers separately, with disagreements about study inclusion resolved by consensus. Randomized trials were eligible for analysis if they included at least one group receiving acupuncture needling and one group receiving either sham (placebo) acupuncture or no acupuncture control. Trials must have accrued patients with one of four indications - non-specific back or neck pain, shoulder pain, chronic headache or osteoarthritis - with the additional criterion that the current episode of pain must be of at least four weeks duration for musculoskeletal disorders. There was no restriction on the type of outcome measure, although we specified that the primary endpoint must be measured more than four weeks after the initial acupuncture treatment.

It has been demonstrated that unconcealed allocation is the most important source of bias in randomized trials[7] and, as such, we included only those trials where allocation concealment was determined unambiguously to be adequate (further detail in the review protocol[6]). Where necessary, we contacted authors for further information concerning the exact logistics of the randomization process. Trials were excluded if there was any ambiguity about allocation concealment.

Data Extraction and Quality Assessment

The principal investigator of eligible studies was contacted and asked to provide raw data from the trial. To ensure data accuracy, all results reported in the trial publication, including baseline characteristics and outcome data, were then replicated.

Reviewers assessed the quality of blinding for eligible trials with sham acupuncture control. Trials were graded as having a low likelihood of bias if either the adequacy of blinding was checked by direct questioning of patients (e.g. by use of a credibility questionnaire) and no important differences were found between groups, or the blinding method (e.g. the Streitberger sham device[8]) had previously been validated as able to maintain blinding. Trials with a high likelihood of bias from unblinding were excluded from the meta-analysis of acupuncture versus sham; a sensitivity analysis included only trials with a low risk of bias.

Data Synthesis and Analysis

Each trial was reanalyzed by analysis of covariance with the standardized principal endpoint (scores divided by pooled standard deviation) as the dependent variable, with the baseline measure of the principal endpoint and variables used to stratify randomization as covariates. This approach has been shown to have the greatest statistical power for trials with baseline and follow-up measures.[9, 10] The effect size for acupuncture from each trial was then entered into a meta-analysis using the *metan* command in Stata 11 (Stata Corp., College Station, TX): the meta-analytic statistics were created by weighting each coefficient by the reciprocal of the variance, summing and dividing by the sum of the weights. Meta-analyses were conducted separately for comparisons of acupuncture with sham and no acupuncture control, and within each pain type. We pre-specified that the hypothesis test would be based on the fixed effects analysis as this constitutes a valid test of the null hypothesis of no treatment effect.

Results

Systematic review

We identified 82 trials (see figure 1 for flowchart) of which 31 were eligible (Table 1 and Appendix online). Four of the studies were organized as part of the German Acupuncture Trials (GERAC) initiative[11–14], 4 were part of the Acupuncture Randomized Trials (ART) group[15–18]; 4 were Acupuncture in Routine Care (ARC) studies[19–22]; 3 were UK National

Health Service acupuncture trials[23–25]. Eleven studies were sham controlled, 10 had no acupuncture control and 10 were three-armed studies including both sham and no acupuncture control. The second search for subsequently published studies identified an additional four eligible studies[26–29], with a total of 1,619 patients.

An important source of clinical heterogeneity between studies concerns the control groups. In the sham controlled trials, the type of sham included acupuncture needles inserted superficially[13], sham acupuncture devices with needles that retract into the handle rather than penetrate the skin[30] and non-needle approaches such as deactivated electrical stimulation[31] or detuned laser[32]. Moreover, co-interventions varied, with no additional treatment other than analgesics in some trials[15], whereas in other trials, both acupuncture and sham groups received a course of additional treatment, such as exercise led by physical therapists[25]. Similarly, the no acupuncture control groups varied between usual care, such as a trial in which control group patients were merely advised to "avoid acupuncture"[23]; attention control, such as group education sessions[33]; and guidelined care, where patients were given advice as to specific drugs and doses[13].

Data extraction and quality assessment

Usable raw data were obtained from 29 of the 31 eligible trials, including a total of 17,922 patients from the US, UK, Germany, Spain and Sweden. For one trial, the study database had become corrupted[34]; in another case, the statisticians involved in the trial failed to respond to repeated enquiries despite approval for data sharing being obtained from the principal investigator[35].

The 29 trials comprised 18 comparisons with 14,597 patients of acupuncture with no acupuncture group and 20 comparisons with 5,230 patients of acupuncture and sham acupuncture. Patients in all trials had access to analgesics and other standard treatments for pain. Four sham-controlled trials were determined to have an intermediate likelihood of bias from unblinding[13, 32, 36, 37]; the 16 remaining sham-controlled trials were graded as having a low risk of bias from unblinding. On average, drop-out rates were low (weighted mean 10%). Drop-out rates were only above 25% for four trials: Molsberger 2002[35] and 2010[27] (33% and 27%, but raw data not received and neither trial included in main analysis); Carlsson 2001[37] (46%, trial excluded in a sensitivity analysis for blinding) and Berman 2004[33] (31%). This had a high drop-out rate amongst no acupuncture controls (43%); drop-out rates were close to 25% in the acupuncture and sham groups. The Kerr trial had a large difference in drop-out rates between groups (acupuncture 13%, control 33%) but was excluded in the sensitivity analysis for blinding[36].

Meta-analysis

Forest plots for acupuncture against sham acupuncture and against no acupuncture control are shown separately for each of the four pain conditions in figures 2 and 3. Meta-analytic statistics are shown in table 2. Acupuncture was statistically superior to control for all analyses ($p<0.001$). Effect sizes are larger for the comparison between acupuncture and no acupuncture control than for the comparison between acupuncture and sham: 0.37, 0.26 and 0.15 in comparison with sham versus 0.55, 0.57 and 0.42 in comparison with no acupuncture control for musculoskeletal pain, osteoarthritis and chronic headache respectively.

For five of the seven analyses, the test for heterogeneity was statistically significant. In the case of comparisons with sham acupuncture, the trials by Vas et al are clear outliers. For example, the effect size of the Vas trial for neck pain is about 5 times greater than meta-analytic estimate. One effect of excluding these trials in a sensitivity analysis (table 3) is that there is no significant heterogeneity in the comparisons between acupuncture and sham.

Moreover, the effect size for acupuncture becomes relatively similar for the different pain conditions: 0.23, 0.16 and 0.15 against sham, and 0.55, 0.57 and 0.42 against no acupuncture control for back and neck pain, osteoarthritis, and chronic headache respectively (fixed effects; results similar for the random effects analysis).

To give an example of what these effect sizes mean in real terms, baseline pain score on a 0 – 100 scale for a typical trial might be 60. Given a standard deviation of 25, follow-up scores might be 43 in a no acupuncture group, 35 in sham acupuncture and 30 in patients receiving true acupuncture. If response were defined in terms of a pain reduction of 50% or more, response rates would be approximately 30%, 42.5% and 50%, respectively.

The comparisons with no acupuncture control show evidence of heterogeneity. This appears largely explicable in terms of differences between the control groups used. In the case of osteoarthritis, the largest effect is for Witt 2005[17], where patients in the waiting list control received only rescue pain medication, and the smallest for Foster 2007[25], which involved a program of exercise and advice led by physical therapists. For the musculoskeletal analyses, heterogeneity is driven by two very large trials[19, 20] (n=2565 and n=3118) for back and neck pain. If only back pain is considered (table 3), heterogeneity is dramatically reduced and is again driven by one trial, Brinkhaus 2006[15], with waiting list control. In the headache meta-analysis, Diener 2006[13] had much smaller differences between groups. This trial involved providing drug therapy according to national guidelines in the no acupuncture group, including initiation of beta-blockers as migraine prophylaxis. There was disagreement within the collaboration about whether this constituted active control. Excluding this trial reduced evidence of heterogeneity (p=0.04) but had little effect on the effect size (0.42 to 0.45).

Table 3 shows several pre-specified sensitivity analyses. Neither restricting the sham control trials to those with low likelihood of unblinding nor adjustment for missing data had any substantive effect on our main estimates. Inclusion of summary data from trials for which raw data were not obtained (2 trials) or which were published recently (4 trials) also had little impact on either the primary analysis (table 3) or the analysis with the outlying Vas trials excluded (data not shown).

To estimate the potential impact of publication bias, we entered all trials in to a single analysis and compared the effect sizes from small and large studies[38]. We saw some evidence that small studies had larger effect sizes for the comparison with sham (p=0.023) but not no acupuncture control (p=0.7). However, these analyses are influenced by the outlying Vas trials, which were smaller than average, and by indication, as the shoulder pain trials were small and had large effect sizes. Tests for asymmetry were non-significant when we excluded Vas and shoulder pain studies (n=15; p=0.065) and when small studies were also excluded(n<100, n=12; p=0.3). Nonetheless, we repeated our meta-analyses excluding trials with a sample size less than 100. This had essentially no effect on our results. As a further test of publication bias, we considered the possible effect on our analysis if we had failed to include high-quality, unpublished studies. Only if there were 47 unpublished trials with n=100 showing an advantage to sham of 0.25 standard deviations would the difference between acupuncture and sham lose significance.

A final sensitivity analysis examined the effect of pooling different endpoints measured at different periods of follow-up. We repeated our analyses including only pain endpoints measured at 2 – 3 months after randomization. There was no material effect on results: effect sizes increased by 0.05 to 0.09 SD for musculoskeletal and osteoarthritis trials and were stable otherwise.

As an exploratory analysis, we compared sham to no acupuncture control. In a meta-analysis of 9 trials[11–13, 15–18, 25, 33], the effect size for sham was 0.33 (95% C.I. 0.27, 0.40) and 0.38 (95% C.I. 0.20, 0.56) for fixed and random effects models respectively ($p<0.001$ for tests of both effect and heterogeneity).

Comment

Overview of findings

In an analysis of patient-level data from 29 high quality randomized trials, including 17,922 patients, we found statistically significant differences between both acupuncture versus sham and acupuncture versus no acupuncture control for all pain types studied. After excluding an outlying set of studies, meta-analytic effect sizes were similar across pain conditions.

The effect size for individual trials comparing acupuncture to no acupuncture control did vary, an effect that appears at least partly explicable in terms of the type of control used. As might be expected, acupuncture had a smaller benefit in patients who received a program of ancillary care – such as physical therapist led exercise[25] – than in patients who continued on usual care. Nonetheless, the average effect, as expressed in the meta-analytic estimate of approximately 0.5 standard deviations, is of clear clinical relevance whether considered either as a standardized difference[39] or when converted back to a pain scale. The difference between acupuncture and sham is of lesser magnitude, 0.15 to 0.23 standard deviations.

Limitations

Neither study quality nor sample size appear to be a problem for this meta-analysis, on the grounds that only high quality studies were eligible and the total sample size is large. Moreover, we saw no evidence that publication bias, or failure to identify published eligible studies, could affect our conclusions.

As the comparisons between acupuncture and no acupuncture cannot be blinded, both performance and response bias are possible. Similarly, while we considered the risk of bias of unblinding low in most studies comparing acupuncture and sham acupuncture, providers obviously were aware of the treatment provided and, as such, a certain degree of bias of our effect estimate for specific effects cannot be entirely ruled out. However, it should be kept in mind that this problem applies to almost all studies on non-drug interventions. We would argue that the risk of bias in the comparison between acupuncture and sham acupuncture is low compared to other non-drug treatments for chronic pain, such as cognitive therapies, exercise or manipulation, which are rarely subject to placebo control.

Another possible critique is that the meta-analyses combined different endpoints, such as pain and function, measured at different times. However, results did not change when we restricted the analysis to pain endpoints measured at a specific follow-up time, 2 – 3 months after randomization.

Comparison with other studies

Many prior systematic reviews of acupuncture for chronic pain have had liberal eligibility criteria, accordingly included trials of low methodologic quality, and then came to the circular conclusion that weaknesses in the data did not allow conclusions to be drawn[40, 41]. Other reviews have not included meta-analyses, apparently due to variation in study endpoints[42, 43]. We have avoided both problems by including only high quality trials and obtaining raw data for individual patient data meta-analysis. Some more recent systematic reviews have published meta-analyses[44–46 47] and reported findings that are broadly

comparable to ours with clear differences between acupuncture and no treatment control and smaller differences between true and sham acupuncture. Our findings have greater precision: all prior reviews have analyzed summary data, an approach of reduced statistical precision when compared to individual patient data meta-analysis [6, 48]. In particular, we have demonstrated a robust difference between acupuncture and sham control that can be distinguished from bias. This is a novel finding that moves beyond the prior literature.

Interpretation

We believe that our findings are both clinically and scientifically important. They suggest that the total effects of acupuncture, as experienced by the patient in routine clinical practice, are clinically relevant, but that an important part of these total effects is not due to issues considered to be crucial by most acupuncturists, such as the correct location of points and depth of needling. Several lines of argument suggest that acupuncture (whether real or sham) is associated with more potent placebo or context effects than other interventions[49–52]. Yet many clinicians would feel uncomfortable in providing or referring patients to acupuncture if it were merely a potent placebo. Similarly, it is questionable whether national or private health insurance should reimburse therapies that do not have specific effects. Our finding that acupuncture has effects over and above sham acupuncture is therefore of major importance for clinical practice. Even though on average these effects are small, the clinical decision made by doctors and patients is not between true and sham acupuncture, but between a referral to an acupuncturist or avoiding such a referral. The total effects of acupuncture, as experienced by the patient in routine practice, include both the specific effects associated with correct needle insertion according to acupuncture theory, non-specific physiologic effects of needling, and non-specific psychological (placebo) effects related to the patient's belief that treatment will be effective.

Conclusion

We found acupuncture to be superior to both no acupuncture control and sham acupuncture for the treatment of chronic pain. Although the data indicate that acupuncture is more than a placebo, the differences between true and sham acupuncture are relatively modest, suggesting that factors in addition to the specific effects of needling are important contributors to therapeutic effects. Our results from individual patient data meta-analyses of nearly 18,000 randomized patients on high quality trials provide the most robust evidence to date that acupuncture is a reasonable referral option for patients with chronic pain.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix

The Acupuncture Trialists' Collaboration includes physicians, clinical trialists, biostatisticians, practicing acupuncturists and others. The list of collaborators is as follows.

Claire Allen is the consumer representative ('patient advocate'). Mrs Allen is the Deputy Administrator at the Cochrane Collaboration Secretariat.

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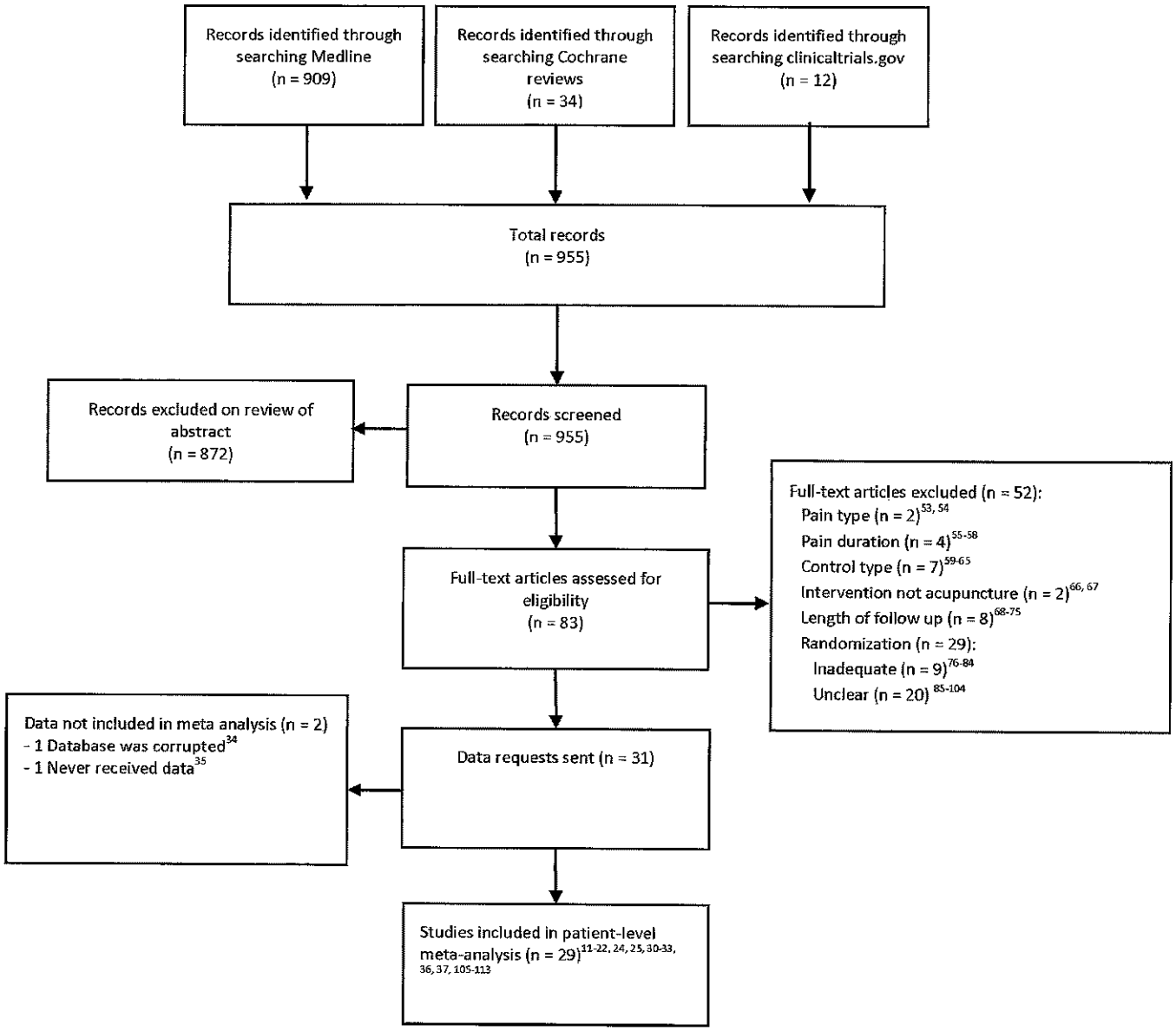


Figure 1.
PRISMA Flow Diagram

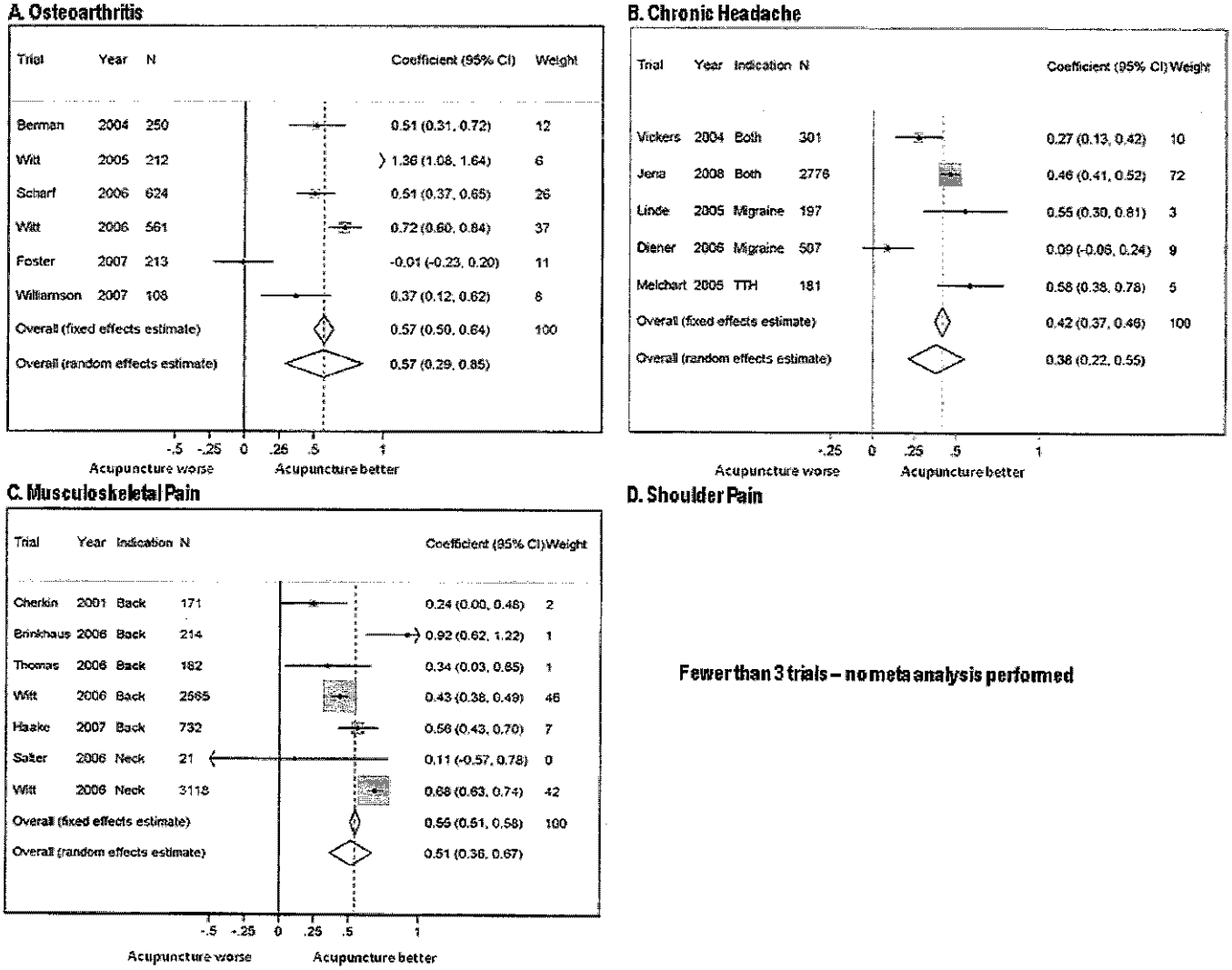


Figure 2.
Forest plots for the comparison of acupuncture with no acupuncture control.

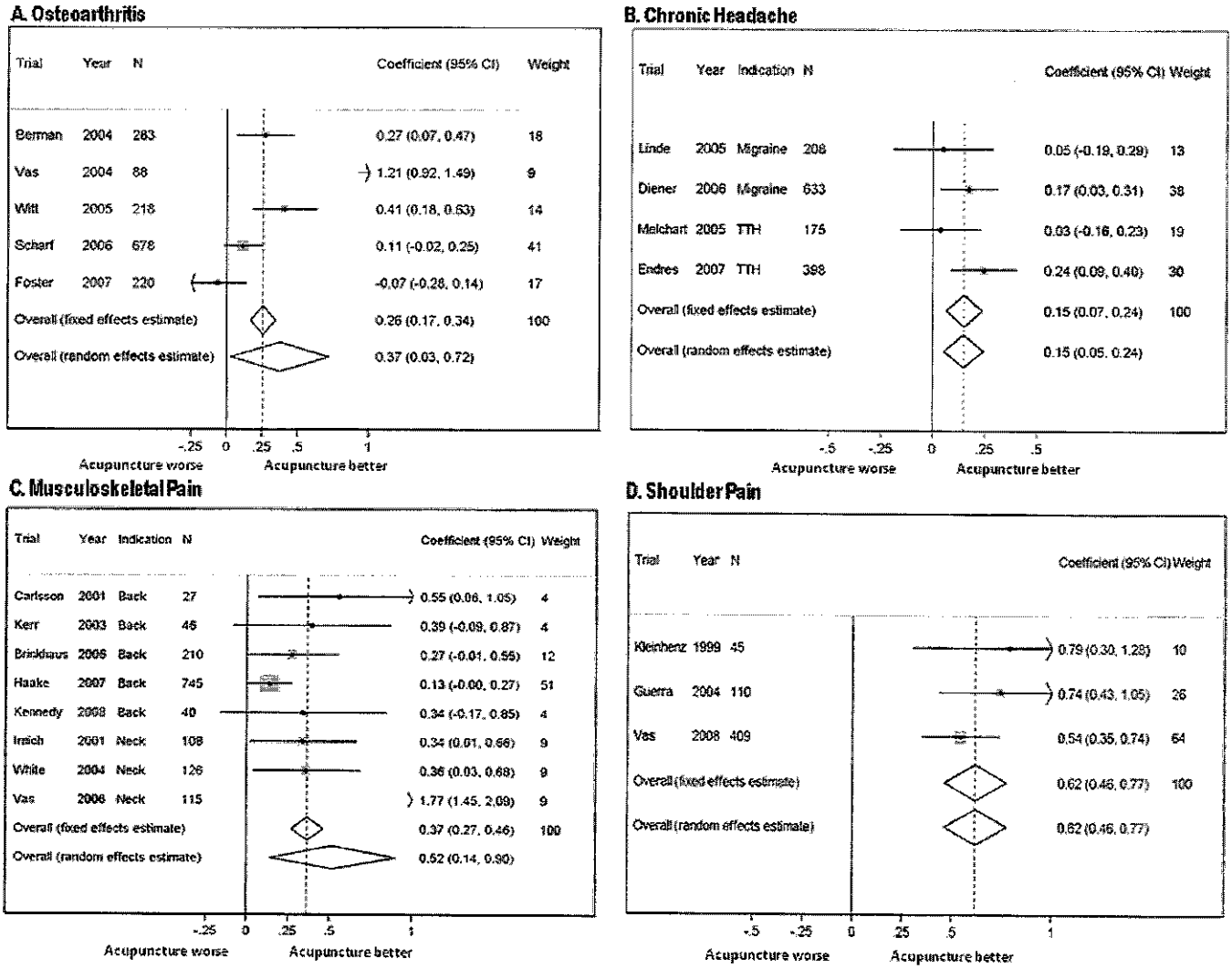


Figure 3.
Forest plots for the comparison of true and sham acupuncture.

Table 1

Characteristics of included studies (Trial level information is provided in the Appendix)

The table includes the 31 trials identified in the initial search plus the four recently identified trials for which summary data were used.

Indication n=35	Pain Type	Control group	Primary Outcome Measure	Time point
Chronic headache n=7	Migraine n=2[13, 18] Tension-type headache n=3[14, 16, 34] Both n=2[21, 53]	Sham n=4[13, 14, 16, 18] No acupuncture control n=6 Ancillary care * n=1[34] Usual care ^ n=4[16, 18, 21, 53] Guidelined care# n=1[13]	Severity score n=2[34, 53] Days with headache n=1[14] Migraine days n=3[13, 16, 21] Days with moderate to severe pain n=1[18]	1 month n=1[34] 3 months n=3[16, 18, 21] 6 months n=2[13, 14] 12 months n=1[53]
Non-specific Musculoskeletal Pain (back and neck) n=15	Back n=10[12, 15, 19, 24, 28, 35–37, 54, 55] Neck n=5[20, 31, 32, 56, 57]	Sham n=10[12, 15, 28, 31, 32, 35–37, 54, 57] No acupuncture control n=9 Ancillary care * n=1[35] Usual care ^ n=6[15, 19, 20, 24, 28, 56] Non specific advice§ n=1[55] Guidelined care# n=1[12]	VAS n=7[15, 31, 32, 35–37, 57] Roland Morris Disability Questionnaire n=3[28, 54, 55] Neck Pain and Disability n=1[20] Hannover Functional Questionnaire n=1[19] Northwick Park Neck Pain Questionnaire n=1[56] Von Korff pain score n=1[12] SF36 Bodily pain n=1[24]	1 month n=4[31, 32, 36, 57] 2 months n=3[15, 28, 55] 3 months n=5[19, 20, 26, 29, 35, 54, 56] 6 months n=2[12, 37] 24 months n=1[24]
Osteoarthritis n=9		Sham n=6[11, 17, 25, 26, 33, 58] No acupuncture control n=8 Ancillary care * n=2[11, 25, 26] Usual care ^ n=4[17, 22, 29] Non specific advice§ n=2[33, 59]	Oxford Knee Score questionnaire n=1[59] Western Ontario and McMaster Universities Arthritis Index (WOMAC) n=2[17, 22] WOMAC pain subscore n=6[11, 25, 26, 29, 33, 58]	2 months n=2[17, 59] 3 months n=4[22, 26, 29, 58] 6 months n=3[11, 25, 33]
Shoulder pain n=4		Sham n=4[27, 30, 60, 61] No acupuncture control n=1 Usual care ^ n=1[27]	Constant-Murley-score n=2[30, 61] VAS n=2[27, 60]	1 month n=2[30, 61] 6 months n=2[27, 60]

*Ancillary care: Program of care received by both acupuncture and non acupuncture groups (e.g. trial comparing physiotherapy plus acupuncture to physiotherapy alone)

^Usual care: Protocol did not specify treatments received in control group (e.g. trials with 'waiting list control')

§Non specific advice: Patients in control group receive general advice and support ('attention control').

#Guidelined care: Patients in control group received care according to national guidelines

Table 2

Primary analyses

Effect sizes are standardized differences.

	Acupuncture vs. Sham acupuncture				Acupuncture vs. no acupuncture control			
	N	Fixed effects (95%CI)	Random effects (95%CI)	P value for overall effect	N	Fixed effects (95%CI)	Random effects (95%CI)	P value for overall effect
Non-specific musculoskeletal pain (back and neck)	8	0.37 (0.27, 0.46) Heterogeneity: p<0.001	0.52 (0.14, 0.90)	p<0.001	7	0.55(0.51, 0.58) Heterogeneity: p<0.001	0.51 (0.36, 0.67)	p<0.001
Osteoarthritis	5	0.26 (0.17, 0.34) Heterogeneity p<0.001	0.37 (0.03, 0.72)	p<0.001	6	0.57 (0.50, 0.64) Heterogeneity: p<0.001	0.57 (0.29, 0.85)	p<0.001
Chronic headache	4	0.15 (0.07, 0.24) Heterogeneity: p=0.3	0.15 (0.05, 0.24)	p<0.001	5	0.42 (0.37, 0.46) Heterogeneity: p<0.001	0.38 (0.22, 0.55)	p<0.001
Shoulder pain	3	0.62 (0.46, 0.77) Heterogeneity: p=0.4	0.62 (0.46, 0.77)	p<0.001	0	No trials		

Table 3

Sensitivity analyses

Effect sizes are standardized differences.

	Indication	Acupuncture vs. Sham acupuncture				Acupuncture vs. no acupuncture control			
		N	Fixed effects (95%CI)	Random effects (95%CI)	P value for overall effect	N	Fixed effects (95%CI)	Random effects (95%CI)	P value for overall effect
Exclusion of Vas trials	Non-specific musculoskeletal pain	7	0.23 (0.13, 0.33) Heterogeneity: p=0.5	0.23 (0.13, 0.33)	p<0.001	Not applicable			
	Osteoarthritis	4	0.16 (0.07, 0.25) Heterogeneity: p=0.15	0.17 (0.00, 0.35)	p<0.001				
	Shoulder pain	Fewer than 3 trials							
Separate pain types	Back pain	5	0.20 (0.09, 0.31) Heterogeneity: p=0.4	0.20 (0.09, 0.32)	p<0.001	5	0.46 (0.40, 0.51) Heterogeneity: p=0.004	0.49 (0.33, 0.64)	p<0.001
	Neck Pain	3	0.83 (0.64, 1.01) Heterogeneity: p<0.001	0.82 (−0.11, 1.75)	p<0.001	No trials			
Inclusion of trials for which raw data not obtained	Non-specific musculoskeletal pain	10	0.30 (.21, 0.38) Heterogeneity: p<0.001	0.48 (0.14, 0.81)	p<0.001	9	0.55 (0.51, 0.58) Heterogeneity: p<0.001	0.57 (0.42, 0.71)	p<0.001
	Osteoarthritis	6	0.22 (0.14, 0.30) Heterogeneity p<0.001	0.31 (0.02, 0.60)	p<0.001	8	0.58 (0.51, 0.64) Heterogeneity: p<0.001	0.57 (0.33, 0.80)	p<0.001
	Chronic headache	No trials				6	0.42 (0.38, 0.47) Heterogeneity: p<0.001	0.41 (0.25, 0.56)	p<0.001
	Shoulder pain	4	0.57 (0.44, 0.69) Heterogeneity: p= 0.4	0.57 (0.44, 0.69)	<0.001	1	Fewer than 3 trials		
Only trials with low likelihood of bias for blinding	Non-specific musculoskeletal pain	5	0.36 (0.25,0.46) Heterogeneity: p<0.001	0.57 (0.00, 1.14)	p<0.001	Not applicable			
	Osteoarthritis	As for table 2: all trials have a low likelihood of bias for blinding							
	Chronic headache	3	0.14 (0.03, 0.25) Heterogeneity: p=0.18	0.12 (−0.02, 0.27)	p=0.013				
	Shoulder pain	As for table 2: all trials have a low likelihood of bias for blinding							
Multiple imputation for missing data	Non-specific musculoskeletal pain	8	0.36 (0.27, 0.46) Heterogeneity: p<0.001	0.52 (0.15, 0.88)	p<0.001	7	0.55 (0.51, 0.58) Heterogeneity: p<0.001	0.51 (0.36, 0.66)	p<0.001
	Osteoarthritis	5	0.25 (0.16, 0.33) Heterogeneity: p<0.001	0.37 (0.03, 0.71)	p<0.001	6	0.57 (0.50, 0.64) Heterogeneity: p<0.001	0.57 (0.29, 0.85)	p<0.001
	Chronic headache	4	0.16 (0.07, 0.25) Heterogeneity: p=0.4	0.16 (0.07, 0.25)	p<0.001	5	0.42 (0.38, 0.46) Heterogeneity: p<0.001	0.38 (0.22, 0.55)	p<0.001
	Shoulder pain	3	0.62 (0.46, 0. 78)	0.62 (0.46, 0.78)	p<0.001	No trials			

Indication		Acupuncture vs. Sham acupuncture				Acupuncture vs. no acupuncture control			
	N	Fixed effects (95%CI)	Random effects (95%CI)	P value for overall effect	N	Fixed effects (95%CI)	Random effects (95%CI)	P value for overall effect
		Heterogeneity: p=0.4						

APPENDIX A

Request Form for Board of Trustee Consideration of a Change to SHP Benefits

This form is to be used by individuals or groups that would like to propose new benefits coverage or request changes to benefits already covered by the State Health Plan. Please read the Procedure – Requests for Benefits Changes, SHP-PRO-7001-SHPfor more information regarding these types of requests.

Please submit completed forms by email to SHP.Board@nctreasurer.com or mail to NC State Health Plan Board of Trustees, 4901 Glenwood Avenue, Suite 300, Raleigh, NC 27612-3638.

Name of Requestor: Chuck Stone, SEANC

Contact Information (*phone, email, mailing address*):
1621 Midtown Place, Raleigh, NC, 27609, cstone@seanc.org, 919-833-6436

Requested Change in Benefits Coverage: See attachments

Reason for Request: see attachments

Proposed Effective Date of Change: see attatchments

Supporting Documentation (*Please provide documents to support your request; examples include research or studies regarding medical services, treatment or procedures, fiscal impact analyses if available, or petitions from members.*):

Would you like to speak with the Board of Trustees about this issue at a Board of Trustees meeting?

The Board of Trustees reviews select requests annually at a regularly scheduled Board of Trustee meeting. For calendar year 2013, requests will be reviewed at the November meeting. For calendar year 2014, requests will be reviewed at the July meeting. Review of requests in no way obligates the State Treasurer to make changes to benefits.

DST Reference:	**SHP-PRO-7001-SHP**
Title:	**Procedure - Requests for Benefit Changes**
Cross Reference:	**n/a**
Chapter:	**State Health Plan Board of Trustees**
Current Effective Date:	**November 6, 2013**
Revision History:	
Original Effective Date:	**November 6, 2013**

Applies to: **NC Department of State Treasurer – SHP Division**

Keywords: Board of Trustees, benefits, coverage, presentation, meeting, changes

Purpose

The purpose of this procedure is to provide a process for the public to communicate with the State Health Plan Board of Trustees regarding requests for changes to member benefits coverage. This procedure is specifically targeted towards groups or individuals that may represent the interest of certain segments of State Health Plan membership as it relates to their health and health care.

Related Statutes, Rules, and Policies

The By-Laws for the North Carolina State Health Plan Board of Trustees provide that one meeting per year will be used to review requests made by individuals or groups for changes in benefits under the State Health Plan.

Procedure

In fulfilling its mission to improve the health and health care of North Carolina teachers, state employees, retirees, and their dependents, this procedure establishes a forum for individuals or groups to propose changes in benefits coverage to the State Health Plan Board of Trustees. The Board of Trustees will designate one meeting per calendar year to review requests for changes in benefits coverage that are submitted by the public in accordance with this procedure.

Implementation

- Individuals or groups wishing to request changes to benefits must complete a *"Request Form for Board of Trustee Consideration of a Change to SHP Benefits."* The required form is attached to this procedure as Appendix A.
- Request forms should be submitted by email to SHP.Board@nctreasurer.com or mailed to: NC State Health Plan Board of Trustees, 4901 Glenwood Avenue, Suite 300, Raleigh, NC 27612-3638.
- The Board of Trustees will designate one meeting each calendar year to review requests. Not all requests may be reviewed at the meeting; whether or not a request will be reviewed at the designated meeting is at the discretion of the State Treasurer.
- Requestors will be allowed to present or address the Board of Trustees at the discretion of the State Treasurer.
- If the requestor will be allowed to address the Board of Trustees regarding the request, notice of the time and place of the meeting will be provided to the requestor at least one week before the designated Board of Trustees meeting.
- Requests submitted to the Board of Trustees for consideration in no way obligates the State Treasurer to allow the requestor to address the Board of Trustees or make changes to benefits.

Revision History

Version/Revision	Date Approved	Description of Changes
V1.0	11/6/13	Initial Procedure

For questions or clarification on any of the information contained in this policy, please contact the procedure owner or designated contact point: (Lotta.Crabtree@nctreasurer.com). For general questions about department-wide policies and procedures, contact the DST Policy Coordinator: Sandra.Johnson@nctreasurer.com.

STATE HEALTH PLAN BENEFIT CHANGE PROPOSALS
STATE EMPLOYEES ASSOCIATION OF NORTH CAROLINA

Presenter: Chuck Stone, Director of Operations SEANC
Contact: (919) 812-2341 or cstone@seanc.org
August 27-28, 2015

Requested Change in Benefits Coverage (SEANC 1): Provide a Medicare Supplement/Medigap Policy or cash benefit for Medicare Retirees with automatic adjustments for health care inflation, age and adverse risk. Alternately, provide a PPO 80/20 Option for Medicare Retirees wishing to maintain Traditional Medicare.

Reason for Request:

1. Many retirees have requested this as an option.
2. Development of a Medicare Supplement option must avoid adverse impact on other State Health Plan options for retirees.

Proposed Effective Date: January 1, 2016 or January 1, 2017

Requested Change In Benefits Coverage (SEANC 2): Provide active, non-retired state employees with the option to select retiree health insurance coverage or free dependent coverage equivalent in value to the current retiree health care coverage. The benefit will be adjusted annually for health care inflation using an appropriate national health care inflation index such as that used by the Center for Medicare Services (CMS). Funding of current unfunded liabilities should be treated the same as state bond indebtedness since the services and costs have already been provided and accrued, and should be honored in accordance with the state motto: "To Be Rather Than to Seem."

Reason for Request:

1. Enable the state to compete with the private sector and local/state/federal government in recruiting and retaining a career workforce more representative of the average workforce age.
2. Reduce unfunded liabilities for future retiree health insurance benefits.
3. Provide greater transparency and accountability to the taxpayers in comparing State Health Plan benefits and costs to large private sector employers; and provide greater budget prediction since future health care costs are difficult or impossible to estimate.
4. Provides accountability by requiring funding on a pay-as-you go basis, rather than the current unfunded liability system.
5. Allow retired military personnel with TriCare for Life to maximize their retiree health insurance benefits.
6. Increase the number of insured North Carolinians since most State Health Plan members cannot afford dependent coverage. The percentage of Adjusted Gross Income to purchase family coverage in the State Health Plan exceeds the level required under the Affordable Care Act mandating health insurance coverage. Thus, many state employees have dependents without insurance coverage resulting in increased costs to those with insurance.

Proposed Effective Date: January 1, 2016 or January 1, 2017

Requested Change in Benefits Coverage (SEANC 3): Provide a <u>combined medical and pharmaceutical maximum out-of-pocket limit</u> not to exceed $5,000 annually per covered member for the PPO options.

Reason for Request:

1. Allows State Health Plan members to budget better for medical expenses.
2. Limits financial liability of State Health Plan members for out-of-pocket expenses which is essential given the lack of pay raises and low salaries.
3. Allows State Health Plan members to focus on job responsibilities rather than medical bills.

Proposed Effective Date: January 1, 2016 or January 1, 2017

Requested Change in Benefits Coverage (SEANC 4): Reduce generic drug copays to a maximum of $10 per script.

Reason for Request:

1. The current generic drug copay of $12 is near the maximum of the scale and not competitive with large employer prescription drug copays for generics.
2. A lower generic drug copay would increase medication adherence and reduce more costly medical care.
3. While state law requires pharmacies to charge State Health Plan members the lesser of the current generic copay, or the price charged to the general public, anecdotal evidence suggests that many pharmacies evade this provision by requiring a pharmacy prescription drug card to qualify for lower generic copays (such as $4 for a one month supply) or automatically defaulting to the $12 generic copay.
4. Save money for State Health Plan members.

Proposed Effective Date: January 1, 2016

Requested Change in Benefits Coverage (SEANC 5): Reestablish a premium free health care benefit equivalent to the current PPO 80/20 and eliminate Wellness Premium Surcharges for the new PPO 80/20. Request General Assembly provide funding for positive cash incentives of $50 for designating a Primary Care Physician and $50 for Completion of a Health Assessment.

Reason for Request:

1. Benefit reductions, premium increases and other changes to the State Health Plan since 2008 cost-shifted an average of $1,300 annually to every active employee/early retiree and $1,000 annually to every Medicare retiree. (General Assembly Fiscal Notes)
2. State Employees have only had a 1.2% pay increase in the past 5 years.
3. While many health insurance plans have begun imposing premium surcharges for smoking, the use of premium surcharges for designation of a Primary Care Physician and Completion of Health Assessments is not routine. Some other health insurance plans provide cash incentives for the Primary Care Physician and Health Assessment.

Proposed Effective Date: January 1, 2016

Requested Change in Benefits Coverage (SEANC 6): Seek coverage for acupuncture benefits in the State Health Plan when performed by health care providers, including non-Medical Doctors, appropriately trained and certified in acupuncture for medical conditions where acupuncture has been proven to have therapeutic medical value.

Reason for Request:

1. Acupuncture has proven to have therapeutic medical value for many medical conditions, thus reducing or eliminating the need for prescription drugs with addiction potential and other adverse side effects.
2. Improve medical outcomes and speed recovery reducing other health care costs.
3. Requirements to cover Accupuncture only when performed by an M.D. limit access in most areas of the state and increase costs for the State Health Plan.

Proposed Effective Date: January 1, 2016

North Carolina
State Health Plan
FOR TEACHERS AND STATE EMPLOYEES

Pharmacy & Therapeutics Committee
May and August 2015 Meeting Summary

Board of Trustees Meeting

August 28, 2015

A Division of the Department of State Treasurer

Updates to Utilization Management Programs

Programs	Update
COX-2 Inhibitor Prior Authorization Policy	Policy updated to add new generic celecoxib.
Sedative Hypnotic Step Therapy & Quantity Limit Policy	Policy updated to add new sedative hypnotic, Belsomra as a Step 2 product.
Topical Acne Step Therapy Policy	Policy updated to add new product, Onextron, as a Step 2 product.
Kalydeco Prior Authorization Policy	Policy updated to add a new FDA-approved indication for R117H mutation.
Tafinlar and Zelboraf Prior Authorization Policies	Policies updated to add a new indication for Non-Small Cell Lung Cancer with BRAF V600E Mutation.
Long Acting Opioid Quantity Limit Policy	Policy updated to add new product, Hysingla ER.

Updates to Utilization Management Programs

Program	Update
Buprenorphine/Buprenorphine-Naloxone Prior Authorization and Quantity Limit Policy	Policy updated to add new strength of Zubsolv 8.6/2.1 mg.
Hepatitis C Prior Authorization Policies	Sovaldi and Olysio policies updated to align with the current AASLD guidelines; added limitations to treat Metavir Stage F2, F3 and F4 unless at high risk of transmitting Hepatitis C Virus.
Cosentyx Prior Authorization	Cosentyx is a new medication with prior authorization criteria added to the Plaque Psoriasis Category.
Attention Deficit/Hyperactivity Disorder Prior Authorization Policy	Policy updated to add the new indication of binge eating disorder for Vyvance. New medication, Evekeo, was added to the policy.
Weight Loss Prior Authorization Policy	Policy updated to add new medication, Saxenda.

Updates to Utilization Management Programs

Programs	Update
Otezla Prior Authorization, Step Therapy and Quantity Limit Policy	Policy updated to add quantity limits to Otezla 55 tablet starter pack/kit.
Revlimid Prior Authorization Policy	Policy updated to add follicular lymphoma (Non-Hodgkin's Lymphoma) as approved criteria.
Thalomid Prior Authorization Policy	Policy updated to add coverage criteria regarding patients with System Light Chain Amyloidosis, Discoid Lupus Erythematosus and Cutaneous Lupus Erythematous, Prurigo Nodularis and Waldenstrom's Macroglobulinemia /Lymphoplasmacytic Lymphomas. Removed Crohn's Disease as a covered indication.
Omega 3 Fatty Acid Prior Authorization Policy	Policy updated to clarify wording of the criteria; changed from "the patient has tried one or is currently receiving" to "the patient has tried one OTC omega-3 fatty acid product (e.g., fish oil supplements) and has not achieved adequate efficacy according to the prescribing physician."

Updates to Utilization Management Programs

Program	Update
Forteo Prior Authorization Policy	Policy updated to add exclusions: hypoparathyroidism, osteoporosis prevention, concurrent use of Forteo with other medications for osteoporosis.
Androgen Prior Authorization and Step Therapy Policy	Policy updated to add Natesto to the policy and remove First Testosterone Compound Kits from coverage (not an FDA approved drug).
Inhaled Corticosteroid Step Therapy Policy	Policy updated to add Arnuity Ellipta to Step 1.
Proton Pump Inhibitor Step Therapy, Prior Authorization and Quantity Duration Policy	Policy updated to add generic Nexium (esomeprazole) to Step 1. Moved brand Nexium to Step 2. PA criteria for Step 2 products to try Step 1 prescription products.
Bisphosphonate Step Therapy Policy	Policy updated to add generic Actonel (risedronate) tablets and generic Atelvia (risedronate) tablets added to Step 1. Criteria removed regarding exceptions for Actonel in patients with Paget's disease who have already started therapy with Actonel tablets.

New Utilization Management Programs

Program	Description	Member Impact	Estimated Projected Savings	P&T Recommendation	Implementation
Overactive Bladder Step Therapy Policy	Step therapy policy promoting generics, Vesicare and Myrbetriq	427	$270,000 (annual)	Yes	June 1, 2015
Orkambi Prior Authorization Policy	A new drug FDA approved for the treatment of cystic fibrosis (CF) in patients ≥ 12 years of age who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene	0	New drug	Added to existing cystic fibrosis therapeutic class	July 20, 2015

New Utilization Management Programs

Program	Description	Member Impact	Estimated Projected Savings	P&T Recommendation	Implementation
Harvoni	Prior Authorization	Current users grand-fathered	Not modeled (new drug)	Yes	March 15, 2015
Viekira Pak	Prior Authorization	Current users grand-fathered	Not modeled (new drug)	Yes	March 15, 2015
PCSK9 Inhibitors and ESI's Cholesterol Care Value Program	Prior Authorization	No users	Not modeled (new drug)	Updated P&T 8/15	July 30, 2015

New Drugs for Formulary Consideration

Drug	Indication	Tier Placement
AFREZZA® (insulin human [rDNA origin] inhalation powder)	Type 1 Diabetes Mellitus	3
INVOKAMET (canagliflozin and metformin hydrochloride)	Type 2 Diabetes Mellitus	2
TANZEUM (albiglutide for subcutaneous injection)	Type 2 Diabetes Mellitus	3
ACTICLATE (doxycycline hyclate USP)	Antibacterial	3
JUBLIA (efinaconazole topical solution, 10%)	Topical antifungal	3
KERYDIN (tavaborole topical solution, 5%)	Topical antifungal	3
ARNUITY ELLIPTA (fluticasone furoate inhalation powder)	Asthma	2

New Drugs for Formulary Consideration

Drug	Indication	Tier Placement
STRIVERDI RESPIMAT (olodaterol inhalation)	Chronic Obstructive Pulmonary Disease	2
AURYXIA (ferric citrate tablets)	Chronic kidney disease phosphate binder	3
BUNAVAIL (buprenorphine/naloxone buccal film)	Opioid dependence	3
CONTRAVE (naltrexone HCl/bupropion HCl ER tablets)	Chronic weight management	3
PROAIR RESPICLICK (albuterol inhaler)	Asthma and Chronic Obstructive Pulmonary Disease (COPD)	2
QUDEXY XR (topiramate ER)	Seizures	3

New Drugs for Formulary Consideration

Drug	Indication	Tier Placement
RASUVO (methotrexate auto-injector)	Active rheumatoid arthritis and polyarticular juvenile idiopathic arthritis	3
VOGELXO (testosterone gel)	Low testosterone in males	3
AKYNZEO (netupitant and palonosetron capsules)	Prevention of acute and delayed chemotherapy induced nausea and vomiting	3

Additional Topics Discussed

- Enhancement to ESI's Compound Management Solution
  - ESI's Compound Management Solution was enhanced to exclude selected tablets and capsules from compound ingredients effective June 22, 2015. Prenote was sent to members impacted on May 22, 2015.
  - SHP's current Compound prior authorization policy was discontinued since the five ingredients (ketamine, gabapentin, diclofenac, ketoprofen, and flurbiprofen) that are blocked in the policy are included in ESI's Compound Management Solution enhancement.
  - Existing prior authorizations for compounds will be honored for the duration of the approved prior authorization.

Additional Pharmacy Update

- Effective September 1, 2015, the Plan will no longer cover selected Pain Patches and Compound Kits.
- These products are NOT “FDA approved drugs,” but are “Unapproved Other Marketing Category.”
- These products are “ZB” type, which indicates that a product is sold as a prescription pharmaceutical entity that has not been evaluated by the FDA.
- Prenote was sent August 1, 2015, to members impacted.

North Carolina
State Health Plan
FOR TEACHERS AND STATE EMPLOYEES

Wellness Wins Pilot Update

Board of Trustees Meeting

August 28, 2015

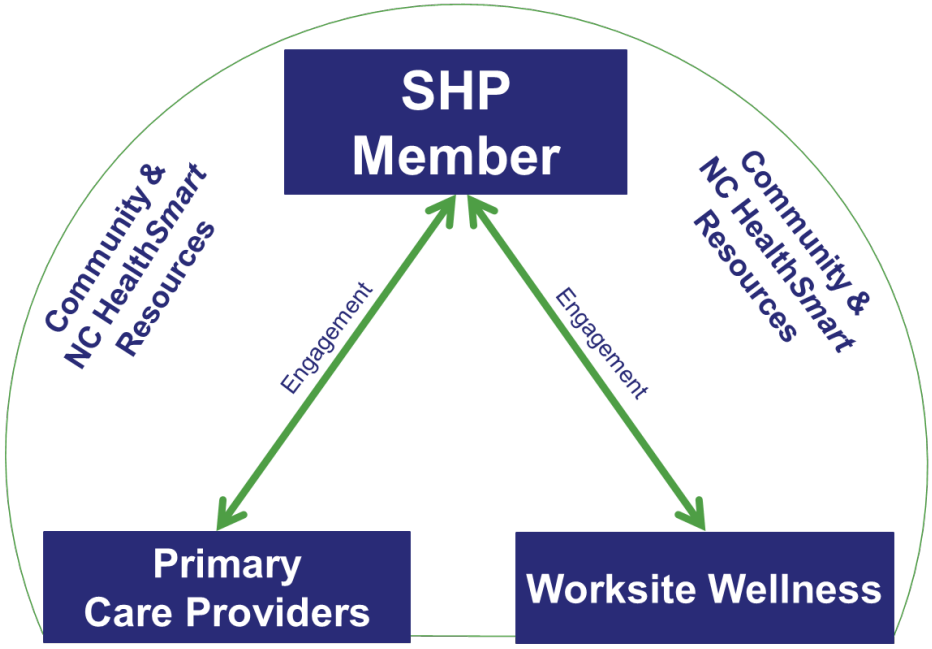
A Division of the Department of State Treasurer

Wellness Wins Model

Goal: Develop a replicable model for enhancing member health through engagement of primary care practices, worksites, and community resources.

Objectives:

- Establish sustainable worksite wellness programs
- Increase member awareness of and engagement in their own health
- Increase member engagement with medical homes/Primary Care Providers



Wellness Wins Milestones

- **Letter of Support**
  - Letters from Treasurer Cowell sent to local leaders encouraging participation
- **Stakeholder Roundtable**
  - 40 wellness, worksite, and community leaders attended to learn about the initiative and provide feedback
- **Biometric Screenings**
  - 118 State Health Plan members participated in a biometric screening
- **Leadership Meetings**
  - Promotional meetings held with key school and correctional leaders including Superintendents, Human Resource Directors, Principals, and wellness leaders
- **Contracts**
  - Prevention Partners will help develop worksite wellness programs with state agencies within initiative
  - Division of Public Health: Obesity, Diabetes, Heart Disease and Stroke Prevention Funding (ODHDSP) will help develop worksite wellness programs with schools within initiative
  - University of North Carolina will develop the Collaborative Referral Network and resource inventory
  - *Pending contract* with Community Care of North Carolina (CCNC) for practice transformation support

Worksite Wellness Program Strategies

- Designate a wellness leader to serve as the main contact for the State Health Plan and supporting partners
  - This employee would ideally invest **4-6 hours** each month making wellness a priority at their worksite
- Organize a wellness committee and meet regularly to assess, implement, and discuss future wellness programs
- Complete a worksite wellness assessment
- Identify priority areas for worksite wellness initiatives
- Establish annual worksite wellness goals and objectives
- Offer health promotion activities
- Encourage employee participation

Sustainability Resources: Worksites

- **Collaborative Referral Network**:
  - Led by the University of North Carolina
  - Will offer a resource inventory for topic areas addressed in the CDC Health ScoreCard
- **Wellness Champions Program offering**:
  - Opportunities to earn incentives towards worksite wellness programs
  - Health promotion materials including monthly newsletters
  - Quarterly webinars on worksite wellness
- **Prevention Partners and ODHDSP:**
  - Help worksites develop independent and sustainable workplace wellness programs

Wellness Wins Next Steps

2015

August-December	• Recruitment of worksites to participate • Introductory meetings between worksites, Plan, and partners
October-November	• Worksite Wellness Training for school wellness leaders
November-December	• Financial stability web-training

2016

January-March	• Worksite wellness networking meeting • Diabetes prevention, awareness, and management campaign
April-June	• Heart disease prevention, awareness, and management campaign • Second worksite wellness training for second wave of schools recruited
July-September	• Asthma and COPD prevention, awareness, and management campaign

Intended Outcomes

Member

- Increased awareness of own health status and NC Health*Smart* resources
- Increased participation in worksite wellness programs
- Increased health care literacy of health benefits and utilization of appropriate care

Worksite

- Development and implementation of sustainable worksite wellness programs
- Determine appropriate supports the Plan can provide to impact member health
- Enhanced communication of health benefits and resources offered by the Plan

Provider

- Begin the conversation between the Plan and providers on how we can work together to meet common goals
- Determine what supports practices need to deliver optimal care to their patients

North Carolina
State Health Plan
FOR TEACHERS AND STATE EMPLOYEES

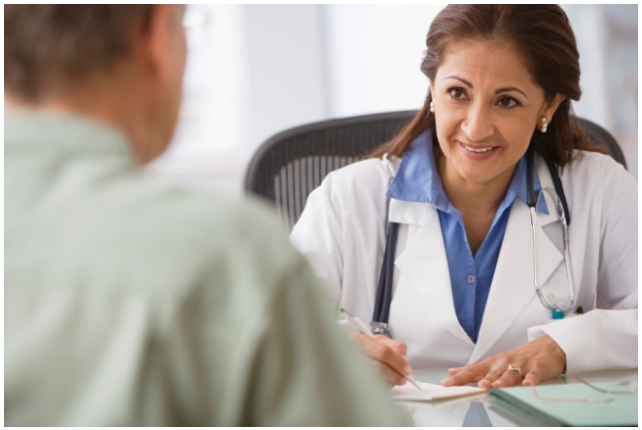
Patient-Centered Medical Home Pilot Update

Board of Trustees Meeting

August 28, 2015

Patient-Centered Medical Home (PCMH) Pilot Vision

- Complement an overall provider engagement strategy
- Engage physicians in the care of Plan members through an alternate payment strategy, data driven, coordinated supports
- Achieve better health outcomes and improve the member's experience in a complex health care environment



Patient-Centered Medical Home Status

- Contracts have been signed with 4 provider groups:
  - CaroMont, May 2015
  - Eagle, May 2015
  - Carolinas HealthCare (New Hanover), May 2015
  - Novant, August 2015
- Baseline and target metrics established for 3 of 4 practice groups

PCMH Status	CaroMont	Eagle	Carolinas HealthCare	Novant
Practices	10	7	3	41
Physicians	95	42	27	778
Members	2,810	4,537	1,593	12,428
Onboarding Tier Level	2	4	4	2

Core Metrics for All Practices

	Measure Name	CaroMont	Eagle	Carolinas Healthcare (NHMG)	Novant Health Systems
	Diabetes Composite	X	X	X	X
Diabetes Composite Measures	HBA1c Test 2x Year				
	LDL Screening				
	Blood Pressure every visit				
	Diabetes Tobacco Assessment				
	Aspirin Therapy				
Asthma Management	Persistent Asthma on ICS	X	X	X	X
Utilization Measures	Rate of ED (Visits per 1000)	X	X	X	X
	Rate of Inpatient Avoidable Hospitalizations (Admits/1000)	X	X	X	X
	Rate of Readmissions	X	X	X	X
	Radiology Costs (PMPY)	X	X	X	X
	Engagement	X	X	X	X

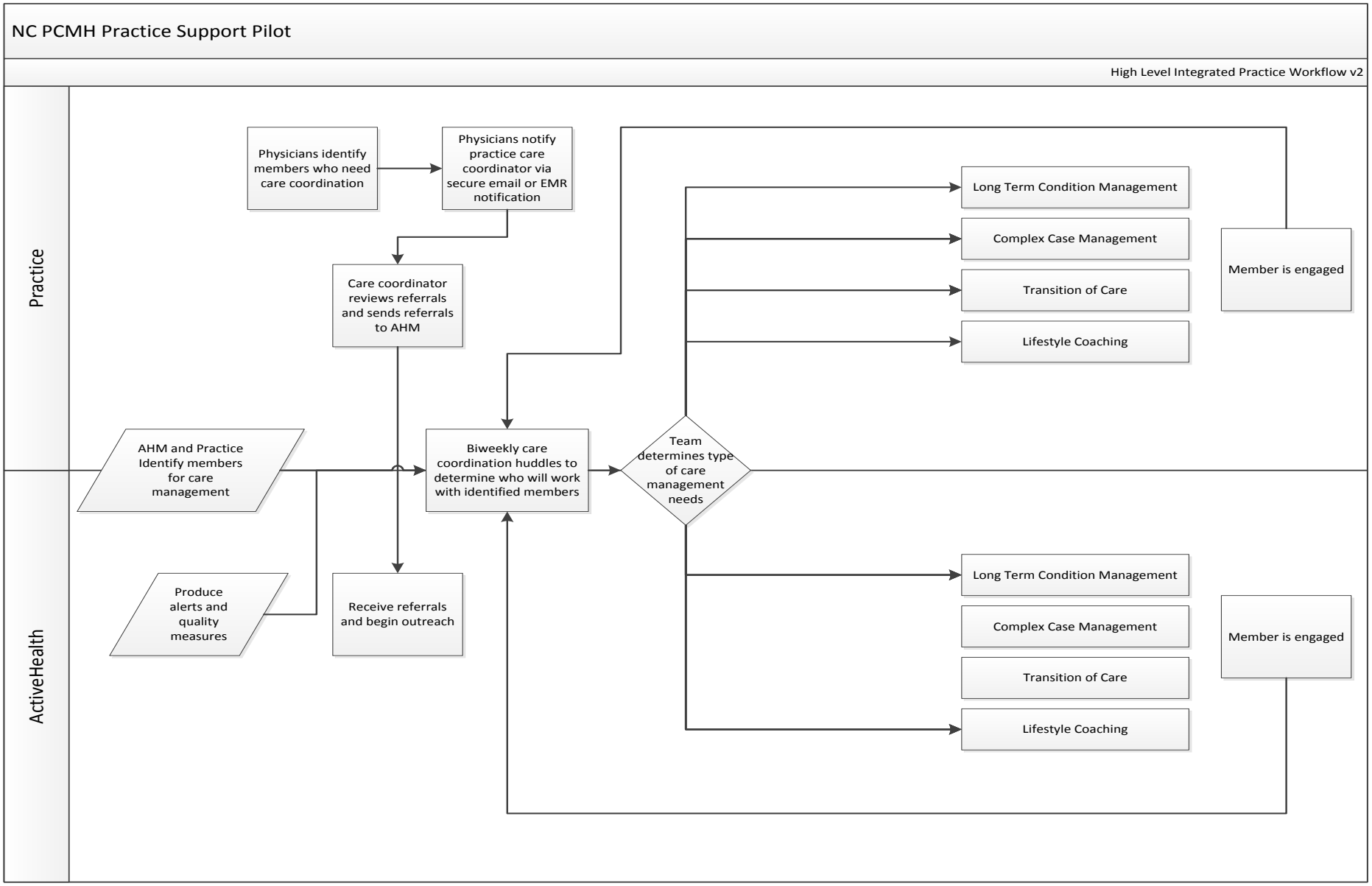
Optional Metrics (Selected by Practices)

Measures		CaroMont	Eagle	Carolinas Healthcare (NHMG)	Novant
Preventive Health	Influenza Vaccine			X	
	Tobacco Screening	X		X	X
	Screening for Clinical Depression and Follow-Up Plan			X	
	Mammogram	X	X		
	Colorectal Cancer	X	X	X	X
CAD Composite*	Ace/ARB for CHF				X
Heart Failure	Beta Blocker for CHF				X
HTN	BP Control (<140/90)	X	X		X
Diabetes	Medical Attention for Nephropathy	X	X	X	X
	Diabetes - HBA1c <7%		X		

Practice Quality Metrics: Baseline (2014)

Core Metrics	Measure Name	CaroMont	Eagle	Carolinas HC	Novant (N.Chlt.)	Novant (WS)
Diabetes Composite Measures	HBA1c Test 2x Year					
	LDL Screening					
	Blood Pressure every visit					
	Diabetes Tobacco Assessment					
	Aspirin Therapy					
	Composite	66%	55%	70.5%	TBD	TBD
Asthma Management	Persistent Asthma on ICS	96.4%	93.50%	95.00%	98.5	95.5
Utilization Measures	Rate of ED Visits per 1000	95.3	101.8	93.6	115.6	116.8
	Rate of Inpatient Avoidable Hospitalizations (Admits/1000)	0.8	1.4	2.7	1.6	2.3
	Rate of Readmissions	8.8%	3%	7.10%	10.6%	9.3%
	Radiology Costs PMPY	$146.17	$83.51	$162.86	$121.7	$151.3
Optional Metrics						
	Influenza Vaccine			47.77%		
	Tobacco Screening	66.40%	82%	90.34%	XX	XX
	Screening for Clinical Depression, follow up			58.9%		
Preventive Health	Mammogram	84.3%				
	Colorectal Cancer	54.8%	58%	TBD	56%	56%
CAD	Ace/ARB for CHF				57.1%	71.4%
Heart Failure	Beta Blocker for CHF				100%	71.4%
HTN	BP Control (<140/90)	65.0%	71%		70%	70%
Diabetes	Medical Attention for Nephropathy	79.3%	91.10	87.60%	84.2	91.3
	Diabetes HBA1c<7%		46%			

Workflow Diagram



Summary and Next Steps

Summary

- PCMH pilot is impacting 21,368 Plan members and over 60 primary care practices
- Establishing EMR based quality metrics (baselines and targets) prove to be the most challenging task
- The PCMH pilot allows a unique collaboration between practices, the Plan and Active Health Management

Next Steps

- Finalize quality metric targets for Novant
- First onsite quarterly Stakeholder meetings at each practice to review operations, accomplishments, and performance results